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Managing Research Information Worldwide.

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**DATATRAK International, Inc.**

**2001 Annual Report and Form 10 - K**

## MISSION AND GROWTH STRATEGY

Our mission at DATATRAK International, Inc. is to assist companies in the pharmaceutical and medical device industries in accelerating the completion of clinical trials by providing improved data quality through the use of our proprietary software. We are a provider of software and other related services, commonly referred to as an application service provider, or ASP. Our customers use our software to collect and transmit clinical trial data electronically, commonly referred to as electronic data capture, or EDC. Our DATATRAK EDC™ software can be deployed anywhere in the world to assist our customers in accelerating clinical drug development, reducing research and development ("R & D") costs, and enhancing the quality of data, thereby producing efficiencies beyond that possible with conventional paper-based clinical trial data collection processes.

The modules that comprise DATATRAK EDC™ provide our customers with a solid foundation from which to re-engineer their clinical research environment. DATATRAK EDC™ is an experienced product that can be deployed globally via a distributed platform using laptop computers, in a centralized environment with resident hardware, or in a wireless mode, all utilizing the Internet.

We believe the clinical research industry will increasingly adopt EDC in order to accelerate clinical development, reduce overall R & D costs and enhance the quality of data. This is a particularly opportune time for significant progress in the EDC arena. The rapid growth of the Internet in e-commerce business solutions has removed many barriers to EDC.

As in any product development effort, and especially in the area of pharmaceutical research, the three most important factors are quality, time and cost. Through the deployment of DATATRAK EDC™, our customers have the opportunity to make their companies more competitive by favorably affecting each of these variables.

Reducing the time and cost of clinical research has never been more important than it is today. Drug development timeframes and their related costs have never been more burdensome. Moreover, advancements made in the rapid discovery of new compounds, in addition to contributions of potential blockbuster drugs from genomic applications, are resulting in growing drug discovery pipelines. These discovery pipelines will require a development magnitude predicted to overwhelm relatively slow-paced and labor-intensive paper processes and further fuel the movement towards EDC.

DATATRAK's growth strategy focuses first on the creation of a market for EDC software and services. Simultaneously, we will be challenged to build an appropriate infrastructure through internal growth and the leveraging of critical strategic alliances and technology transfer relationships to give our customers the confidence that top-notch worldwide EDC process solutions can be delivered. Subsequently, we need to build an expanded market share with our proven product through a satisfied customer base. Progressive positive experiences and the presence of results demonstrating cost and time efficiencies will convince clinical trial sponsors that EDC is capable of creating a new electronic model for clinical research.

## *LETTER TO SHAREHOLDERS*

### **TO OUR FELLOW SHAREHOLDERS**

Evidence indicates that 2001 was yet another critically important year for DATATRAK International, Inc. as it progressively positioned itself as a leading provider of global technology products and services in the emerging Electronic Data Capture (EDC) marketplace. Furthermore, it is believed that moving from 2001 through 2002 will represent a significant transition year as the pharmaceutical and biotechnology industry not only implements EDC at an accelerated frequency, but will increasingly come to the realization that a totally integrated clinical information continuum for clinical trials represents their greatest operational value proposition in the efficient performance of worldwide clinical trials.

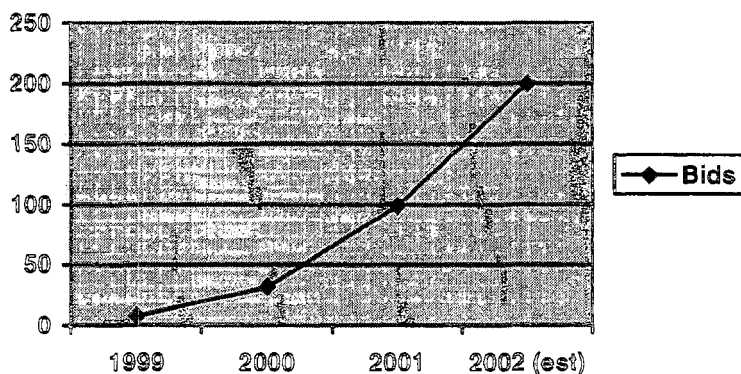
From examination of the 2001 statistics, which are closely tracked by our Company and routinely shared with the market, definitive movement is occurring. Though it remains difficult to predict accurately the adoption rates of technology implementation in this often politically sensitive and interdepartmentally controversial area, there are few today who doubt the increasing use of technology in clinical trials is inevitable. The questions are no longer "why" to implement EDC, but are focused on "how" and "which products and companies" are to be utilized. A successful EDC company has to have both the correct software suite with proven functionality and scalable delivery combined with impeccable service. Technology is a necessary, but an insufficient factor for success in this conservative marketplace – the service component holds at least equal prominence. In general, the characterization of this market and Company after 2001 can be described as progressively positive.

The year of 2001 was also significant for the successful completion of an important Private Investment in a Public Equity (PIPE) transaction, giving DATATRAK International necessary capital to continue with its market progress and also served as the

vehicle for the introduction of new institutional shareholders to an exciting growth potential in an attractive, but emerging market sector.

### *Statistics and Evidence of Market Growth*

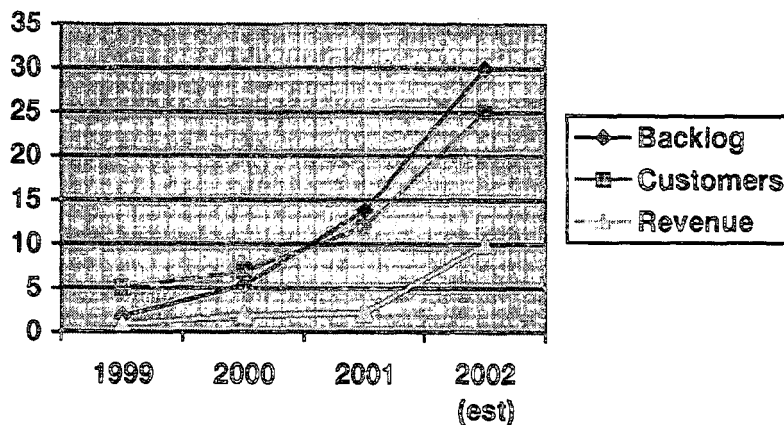
A portion of the objective evidence documenting the Company's progress over the past several years, including that for 2001, is shown in the Figures below.



**Figure 1. Bid Volume for DATATRAK EDC™ Clinical Trials from 1999 to 2002. The Value for 2002 is an Annualized Estimate Based Upon Run Rates from the First Quarter of 2002.**

Since all eventual clinical trials start with a bid from a prospective customer, this is the earliest parameter indicative of market traction. Provided that the estimates for 2002 hold, there will have been a threefold increase in bid activity each of the three years from 1999 through 2002. The total contract value of all bids in 2001 was \$60.6 million. The value of all bids that transitioned into contracts was \$11.7 million for the same period.

The average contract value for all contracted projects in 2001 was \$650,000, which was consistent with the expected deployment of EDC in larger studies. The "win rate" approximated 20%, with most of the lost bids going to traditional paper methodologies.



**Figure 2. Backlog, Customer and Revenue Growth 1999-2002. Values for 2002 are Annualized Estimates Based on Internal Targets.**

Backlog and customer growth closely paralleled the characteristics of bid activity.

The curve for revenue growth is different for several reasons. Most clinical trials last longer than 12 months and many are several years in duration. As such, it is not possible for backlog signed up in any given year to fully translate into revenue. Since DATATRAK International recognizes its revenue as services are delivered consistent with the ASP model, and not through a licensing approach, the Company's revenue recognition, by definition, is dependent upon progress of the clinical trial. Revenue is dependent upon patient enrollment in a time sensitive manner. Additionally, the Company's revenue is at risk for clinical trials being canceled or delayed. On the positive side, DATATRAK EDC™ is capable of producing a renewable revenue stream with each and every clinical trial initiated, unlike the licensing model for more traditional software applications.

Provided that the expected bid activity and conversion into revenue from contracted clinical trials occur without above average delays or cancellation rates, management believes that the published figure of \$10 million in revenue for 2002 is possible. This achievement would represent greater than a fourfold increase in the \$2.2 million in revenue for 2001.

Statistics over the past three years clearly demonstrate a continued emerging of the technology market for clinical trials and corroborate recent consultant reports (e.g., Forrester).

### *DATATRAK International Successfully Competing in this Market*

It is clear from the evidence previously presented that the Company and its product suite are competing successfully in this young market. What cannot be gleaned from this data is the increasing addition of new customers who have initially tried other companies and products, and who have elected to switch to DATATRAK EDC™, often after total market evaluations. Today, there are no fewer than five clients that fit into this category, and the list is expected to grow throughout the year. Though DATATRAK International does not always win every initial selection process, we have an extremely high retention rate of customers (currently, >94%) once they have experienced our unique advantages. Our growth strategies in the marketplace are focused heavily on building reliable reference accounts with such customers, as real life experiences are a heavy driver in the "early adoption phase" of technology implementations.

Our advantages actually play directly into the disadvantages of other product suites in this area, namely that of system performance and ultimate user satisfaction. Our unparalleled user satisfaction rating of 95% in large multinational clinical trials is a testimony that our careful research involving appropriate platforms for thin-client applications back in 1998 resulted in the correct approach. User satisfaction is paramount in the continuance of an electronic clinical trial, and is historically the main reason for past failures in this area. It made eminent sense to solve this problem first and to be able to confidently provide for a rich Internet experience for global users, many of who would be connecting at low bandwidths. One of our new customers who have experienced other systems coined it best by saying, "If you have time to wait, you have time to hate".

The other factor that has contributed greatly to our early progress has been our ability to provide impeccable service to our customers. This service is mostly reflected by a multilingual, 24 x 7 Solutions Center that is responsive to our customers and our users in the fulfillment of their needs. Service is also related to listening to your customers regarding new functionalities that keep them attracted to your technology. DATATRAK International is increasingly being recognized as a Company with a passion for excellence in delivery of technology combined with service, as this is the key to a winning formula in this emerging market.

### ***DATATRAK International as a Technology Leader***

There is not only evidence of market growth, but ample metrics demonstrate that our Company is a true leader in technological innovation. Data supporting this statement within 2001 are:

- Continued advancement of our product suite through the **release of Version 3.1** from an unprecedented software development group with more than seven years of experience in creating superior EDC functionalities; Release of Version 3.2 is scheduled for Spring 2002; Specifications for Version 4.0 are being finalized
- Launched **eTRAIN™** (web-based training product) in multiple clinical trials; DATATRAK was the innovator of web-based training in the EDC market
- Innovator of **eSAT™** (electronic site assessment tool) which allows for remote and independent technical characterization of the ability to perform an EDC trial
- Both **eTRAIN™** and **eSAT™** assist in solving key scalability issues for the global deployment of a large number of clinical trials utilizing EDC and lowers the ultimate cost of EDC deployment compared to manual methods and competitors.
- As a key sponsor of the CDISC Initiative, DATATRAK International successfully participated twice in the "Connectathon" intended to demonstrate functionality of data interchange, which is paramount for integration demands of the future
- Development of a scalable hosting environment that exceeded stringent Service Levels (including >99.5% Availability) with all customers in 2001; the Company

signed a 7-year lease for the creation of a state-of-the-art production hosting facility that will service global clinical trials from its Cleveland, Ohio location; because of the scalability and efficiency of its thin-client platform, DATATRAK International does not require "regional hosting centers"

### *A Rich Audit History*

Regulatory compliance is such a critical component to success in the EDC market that it deserves this year to have its own section in this Letter. A strong Quality Assurance Department is mandatory in order to be selected as a technology of choice by any customer, as the FDA places the burden of utilizing validated systems upon the client. This is yet another reason why the barrier to entry in this business is higher than many expect from a technology application.

DATATRAK International has successfully passed 24 audits from the pharmaceutical, biotechnology and CRO industries in the past 36 months. Time and expense devoted to an average audit is extensive from the customer and vendor standpoint and further emphasizes the serious intentions of the collective clinical trials industry towards the use of technology. Our anticipated move into a state-of-the-art hosting facility in June 2002 will add to our already established credibility in this area.

### *Challenges and Goals for 2002*

- Though substantial progress has been made, the challenge of effectively educating the market continues to be significant. The single most important factor to be taught to the market in 2002 is that not all EDC technologies and companies are the same. There are important distinguishing features that must be understood in order to experience the true benefits of EDC.
- Progressively grow our backlog and revenue quarter-by-quarter so that our shareholders can have a visible barometer of success; DATATRAK International has experienced six consecutive quarters of backlog growth, but in a market that



is expected to increase from approximately \$40 million today to over \$800 million by 2004, much more ground is expected to be quickly covered.

- **Expand our penetration** within current customers and across new clients focusing on the ultimate goal of Enterprise relationships yielding the greatest return for both our customers and our Company, realizing that such Enterprise relationships may take several years to nurture and mature to the fullest extent; this builds a more substantial **barrier to entry** for our competitors in this conservative marketplace
- Develop **five Technology Transfer Level II relationships** during the next 12 months with either clinical trial sponsors or CRO service providers enabling them to utilize our product suite independently for their own corporate advantages and competitive enhancements. Technology Transfer is very important to DATATRAK International as it mitigates headcount as a scalability factor in our business and magnifies the dissemination of our technology by our customers.
- Progressively decrease the burn rate and approach a cash flow breakeven run rate by the end of 2002.
- Continue to invest in and advance our product suite through continuous software development so that DATATRAK EDC™ remains on the forefront of innovation in this market. Continued integration will be paramount to supporting economically significant Enterprise Relationships in the next few years.

### ***Where's This Market Going and How Will DATATRAK Lead It?***

We see progress occurring very quickly over the next eighteen months in three distinct areas. They are:

#### **A. Increased CRO Adoption Rates**

CROs can be significant influencers and supporters of EDC implementation. Over the past few months we have experienced an increase in CRO interest in EDC secondary to an impetus coming directly from sponsors. We have experienced clinical trial sponsors

making their EDC selection first and then contracting with a CRO to manage the global clinical trial. Therefore, the existence of a previous relationship between a CRO and an EDC vendor can make the CRO more competitive towards being awarded a clinical trial, especially to a sponsor who has already decided upon the EDC route. We envision multiple relationships with CROs to be established by the end of 2002.

#### B. Increase in Technology Transfer Relationships

As the use of technology in clinical trials becomes more accepted customers will naturally gravitate towards independence. This has been seen in traditional software applications and will be seen in the EDC arena as well. This phenomenon will begin to accelerate in 2002 and continue over the next several years as late adopters arrive on the scene. DATATRAK International has already launched several Technology Transfer Relationships and it is particularly well suited to deploy many more secondary to our outstanding Design<sup>TM</sup> Module and our simplified business model.

The implementation of Technology Transfer will occur with CROs and sponsors alike and this dissemination route for our products and empowered services has tremendous economic advantages for the Company as the risks and costs of scaling are greatly reduced.

#### C. "Continuum" of Clinical Information Flow in Clinical Trials

The clinical information "Continuum" is currently a hypothetical, integrated functionality of various "components" of technology used to create a consistent and compatible information flow in the clinical development process for drugs and devices. All of the pieces are not hypothetical, however, – several of them are real and produce legitimate functionalities and value to customers today. Despite the presence of isolated electronic tools along this chain, all of the separate "Continuum" functionalities are presently "point solutions" only and are accomplished with varying degrees of inefficiency and unnecessary expense via a clumsy meshing of technology with longstanding paper

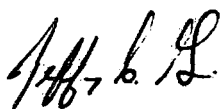
methodologies. "Clumsy" for the sponsor is interpreted as expensive, inefficient, and risky; and is translated for the vendor as market delays; project-by-project commitments and continuation of burn rates while clients wait for the "total solution".

Through integration, information could be continuous from the time of entry at the specific research site and eventually to the point of warehousing. Such integration today, exists only on the drawing board and is envisioned in the future to be accomplished totally with technology in order to maximize improvements in the important parameters of Quality, Time, and Cost that are expended in this regulatory-driven and capital-intensive effort involved in the approval of drugs and devices.

Everyone wants this attractive integrated vision, but no one has it. It is a formidable house to build, but a stable house needs a strong foundation. We believe that strong foundation is a stable and proven EDC platform, which represents the most tangible value proposition along this "Continuum" chain for clinical trials. This is where most of the money and time is spent by the pharmaceutical industry. Furthermore, it is believed that this "Continuum" must be open and not proprietary or restrictive. As such, this integrated platform is unlikely to emanate from within pharma. This "Continuum" will be built by assembling and integrating separate "pieces", some of which currently exist.

The Company that succeeds at this will truly be "Managing Research Information Worldwide".

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey A. Green". The signature is stylized with a large initial "J" and "G".

Jeffrey A. Green, Pharm.D, FCP  
President & CEO

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 10-K**

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

(Mark One) ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

☒ For the fiscal year ended December 31, 2001

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

☐ For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-20699

**DATATRAK International, Inc.**

(Exact name of registrant as specified in its charter)

Ohio

(State or other jurisdiction of  
incorporation or organization)

34-1685364

(I.R.S. Employer  
identification no.)

20600 Chagrin Boulevard, Cleveland, Ohio

(Address of principal executive offices)

44122

(Zip code)

Registrant's telephone number, including area code: (216) 921-6505

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Shares, without par value.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒

No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

As of February 28, 2002, the registrant had 5,263,836 Common Shares, without par value, issued and outstanding. As of that date, the aggregate market value of these shares, which together constitute all of the voting shares of the registrant, held by non-affiliates was \$15,998,855 (based upon the closing price of \$3.30 per Common Share on the Nasdaq Stock Market, Inc. on February 28, 2002). For purposes of this calculation, the registrant deems the 415,698 Common Shares beneficially held by all of its Directors and executive officers to be the Common Shares held by affiliates.

Except as otherwise stated, the information contained in this Form 10-K is as of December 31, 2001.

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## **PART I**

### **ITEM 1. BUSINESS**

#### **General**

We are a provider of software and other related services, commonly referred to as an application service provider, or ASP. Our customers use our software to collect and transmit clinical trial data electronically, commonly referred to as electronic data capture, or EDC. Our customers are companies in the clinical pharmaceutical, biotechnology, contract research organization, or CRO, and medical device research industries. Our services assist these companies in accelerating the completion of clinical trials by providing improved data quality.

We were founded in 1991 as a site management organization, and through our Clinical Business, which we sold in April 1999, provided clinical research services to various clinical trial sponsors. We currently operate as an ASP providing EDC and other services to the clinical research industry.

We began EDC operations in 1997. During that year, we participated in a joint venture with IBM Global Services to develop and market a data collection and management system for use in clinical trials. The joint venture was terminated, and in January 1998, we purchased the software now known as DATATRAK EDC™ from PadCom Clinical Research for \$610,000. Since the purchase of DATATRAK EDC™, we have devoted the majority of our efforts to developing and improving the EDC technology employed by this software.

In January 2002, we received approximately \$4.0 million in connection with the consummation of a private placement of 1,922,514 of our common shares at a purchase price of \$2.25 per share. The terms of this financing included the issuance of five-year warrants to purchase a total of 192,252 common shares, at \$2.25 per share, to Stonegate Securities, Inc., our placement agent for the private placement. We expect to use the proceeds of the private placement to expand our worldwide marketing and sales efforts, continue investing in software development and for other general working capital purposes.

#### **Overview of the Clinical Research Industry**

Our customers are companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industry. This industry is driven by regulatory requirements which mandate that clinical trial sponsors adequately test new drugs and medical devices prior to marketing these drugs and devices. As a result of these regulatory requirements, we estimate that companies in this industry spend approximately \$41.0 billion annually on clinical research, including approximately \$12.0 billion for the collection, analysis and management of clinical trial data.

Competitive and cost-containment pressures are forcing the pharmaceutical and biotechnology industries to become more efficient when developing new products. To improve returns on research and development investments, pharmaceutical and biotechnology companies are continuing to develop new products, while at the same time attempting to shorten product development timelines. These efforts have placed more drugs into the clinical development process and have increased the pressure for companies to develop products faster in order to maintain growth and continue to achieve acceptable returns on research and development expenditures. Clinical trial sponsors have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing clinical research activities.

#### **DATATRAK Software and Services**

Under the traditional method of clinical research, research associates visit research sites to review clinical trial data, which is manually entered on the paper case report form, for accuracy and integrity. During these monitoring visits, the research associate must review each page of each case report form. These visits may last several days, and corrections to the case report forms are frequently required before the data can be

delivered to the research sponsor. Several weeks, or even months, of data may be reviewed during each monitoring visit. At the completion of a monitoring visit, the case report form pages are physically transferred to a central location where the data is then entered into a database for statistical compilation. Using this method of data collection and quality control, the duration of the clinical trial process, from patient visit to delivery of clean data to the clinical trial sponsor, can range from six to nine months. Such delays are significant because errors or trends may not be detected until long after the interaction between the patient and clinical investigator.

We believe that automating data entry and review procedures can save time in the drug development process. Our belief is supported by metrics presented by an international pharmaceutical manufacturer, in 1998. The use of DATATRAK EDC™ in a clinical trial was compared with the traditional, or paper, method of data collection and review in a clinical trial of similar size and complexity. The study showed that DATATRAK EDC™ reduced the overall length of the clinical trial by 30%. Further, the time required to achieve a final, locked database was reduced by 40%, through the use of DATATRAK EDC™. Finally, due to the improved quality of the clinical trial data obtained through the use of DATATRAK EDC™ the study showed an 86% reduction in questions concerning that clinical trial data. We can provide any customer with the DATATRAK® process as a competitive advantage by accelerating the review and processing of clinical trial data.

DATATRAK EDC™ was developed to provide clinical research data to sponsors of clinical research trials faster and more efficiently than other forms of information-processing. The DATATRAK EDC™ software and its earlier versions have supported over 65 international clinical studies involving thousands of clinical research sites and tens of thousands of patients in 34 countries. Our product suite has been utilized in the clinical development of 13 separate drugs that have received regulatory approval from either the FDA or counterpart regulatory bodies in Europe.

DATATRAK EDC™ is a technology platform that consists of Windows™ compatible software and hardware designed to assist clinical trial sponsors in starting and finishing their clinical trials on a more timely basis. Our combination of software and hardware expedites the data collection and reporting process during a clinical trial. In addition to providing technology, we are also a service business that offers EDC and clinical trial data management capabilities across numerous research sites. Our objective is to improve the traditional process of collecting clinical research and noninterventional health care data by providing cleaner data more quickly than what is available in a paper environment.

The DATATRAK EDC™ system consists of five modules designed for flexible adaptation to the clinical research process. We initially provide a set of electronic data forms that can be modeled to suit the needs of each particular clinical trial. Each form is then made available through data entry capability to each research site participating in the clinical trial via the Internet or dial-up connection. Once clinical trial data has been collected and entered, the clinical trial sponsor, or other contracted vendor, can review the data remotely via the Internet or dial-up connection. After the data is reviewed and cleansed of all entry errors, DATATRAK EDC™'s report capability can generate customized reports. Finally, the software's export feature allows completed data and reports to be transmitted directly to a clinical trial sponsor's in-house database. Under this model, research data is collected more quickly and with greater accuracy than with physical review of paper reports.

The DATATRAK EDC™ software can be deployed globally via a distributed platform using laptop computers, in a centralized environment with resident hardware, or in a wireless mode, all utilizing the Internet.

#### Customers and Marketing

Our customers are largely comprised of clinical trial sponsors. We market our software and services through a sales and marketing staff located in the United States and Europe. Since the market for EDC in general, and for our services specifically, has been an emerging one, the effectiveness of our marketing efforts has been limited. However, we have selectively participated in scientific and medical meetings to promote



our services and have occasionally used direct mail and journal advertisements to build awareness of our capabilities.

The EDC market has been slow to develop. The growth of the Internet has drastically altered business strategies and pricing models in this specific sector. Most EDC vendors have insignificant revenues and are classified as start-ups. Nonetheless, we believe that some type of automation in the collection and review of clinical trial data is inevitable.

It is our belief that DATATRAK EDC™ can be competitive in this emerging marketplace. Our product has been tested and verified to be in compliance with FDA and other regulations. Also, DATATRAK EDC™ can be used via the Internet and can be used in multiple languages. Furthermore, a clinical trial sponsor has published statistics indicating that DATATRAK EDC™ can reduce the length of time to complete a clinical trial, and can reduce the number of questions concerning the clinical trial data thereby improving the quality of the clinical trial data.

During 2001 and 2000, Quintiles, Inc. accounted for 11% and 52% of our revenue, and Aventis Pharmaceuticals, Inc. accounted for 22% and 27% of our revenue. Furthermore, during 2001, Control Delivery Systems, Inc. and CV Therapeutics, Inc. accounted for 23% and 21% of our revenue.

### **Contracting and Backlog**

Our contracts with our customers provide a fixed price for each component or service to be delivered, and we recognize revenue as these components or services are delivered. Services provided by us that are in addition to those provided for in our contracts are billed on a fee-for-service basis as completed. Generally, these contracts range in duration from one to three years. The ultimate contract value is dependent upon the length of the customer's use of DATATRAK EDC™ and the services we provide. As services are performed over the life of the contract, we recognize revenue per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Our customers, with or without cause, can terminate a contract at any time. If one of our contracts is cancelled, we are entitled to payment for all work performed through the date of notice of termination and for recovery of some or all costs incurred to terminate a contract. The termination of a contract will not result in a material adjustment to the revenue or costs we have previously recognized.

We are also a seller and licensor of software. Generally, we recognize revenue upon delivery of sold software. Licensing revenue is recognized ratably over the life of the license. To date we have not recognized any revenue from software sales.

Our backlog consists of anticipated revenue from letters of intent and signed contracts yet to be completed. We do not include in our backlog potential contracts or letters of intent that have passed the verbal stage, but have not yet been signed. At December 31, 2001, our backlog was \$11.9 million. Backlog includes a \$2.4 million contract, which is currently on hold. Our backlog, at any point in time, is not an accurate predictor of future levels of revenue.

### **Competition**

We compete within the clinical research and the EDC markets. Both of these industries are highly competitive and fragmented. In addition, the EDC industry is currently emerging and is characterized by rapidly evolving technology. We compete in this market on the strength of DATATRAK EDC™'s functionality, design architecture and data entry and review tools, which we believe equal or exceed those available in the market. We believe that we may be able to enhance our competitive strength through the formation of strategic alliances with established industry organizations. We have received expressions of interest from various parties in establishing such relationships.

Our major competitors include software vendors specializing in EDC, clinical trial data service companies, large pharmaceutical companies currently developing their own in-house technology and the traditional paper-based method of collecting clinical trial data. Also, many current and potential future

competitors have or may have substantially greater financial and technical resources, greater name recognition and more extensive customer bases that could be leveraged, thereby gaining market share or product acceptance to our detriment. We may not be able to capture or establish the market presence necessary to effectively compete in this emerging sector of the clinical research industry. EDC may not effectively replace paper as the preferred method of collecting and managing clinical trial data to the extent that we believe it will.

We are aware of other EDC systems that compete or, in the future, may compete directly with DATATRAK EDC™. We are also aware of other current or developing technologies that provide some of the functionality of the DATATRAK® process. There are other companies that have developed or are in the process of developing technologies that are, or, in the future, may be, the basis for competitive products in the clinical research EDC market. Some of those technologies may have an entirely different approach or means of accomplishing the desired effects of DATATRAK EDC™. Either existing or new competitors may also develop products that are superior to or that otherwise achieve greater market acceptance than DATATRAK EDC™. In addition, we believe that certain large companies in the information technology industry may be forming alliances and attempting to capitalize on the data delivery options offered by the Internet. To the extent that our approach to EDC may gain market acceptance, larger companies in the information technology industry may develop competing technology to our detriment.

#### Regulatory Matters

The FDA has issued guidelines and rules on the use of computer systems in clinical trials relating to standard operating procedures, data entry, system design, security, system dependability and controls, personnel training, records inspection and certification of electronic signatures. Based on our review, we believe DATATRAK EDC™ complies with these guidelines and rules. Because the FDA's guidance and rules are still developing, DATATRAK EDC™ may not remain consistent with the FDA's requirements. Any release of additional FDA guidance that is significantly inconsistent with the design of DATATRAK EDC™ could cause us to incur significant costs in order to change our software. We intend to continue to monitor the FDA's guidance to ensure compliance.

#### Potential Liability and Insurance

Our services are supported by telecommunications equipment, software, operating protocols and proprietary applications for high-speed transmission of large quantities of data among multiple locations. In such operations, it is possible that data files may be lost, altered or distorted. DATATRAK EDC™ and future enhancements or adaptations may contain undetected design faults and software "bugs" that, despite our testing, are discovered only after the system has been installed and used by customers. Such faults or errors could cause delays or require design modifications on our part. In addition, clinical pharmaceutical and medical device research requires the review and handling of large amounts of patient data. Potential liability may arise from a breach of contract or a loss of or unauthorized release of clinical trial data. We obtain contractual agreements from our customers limiting our liability for damages resulting from errors in the transportation and handling of data. Nevertheless, we may still be subject to significant claims for data losses in the transportation and handling of data over our information technology network.

If we were forced to undertake the defense of, or were found financially responsible for, claims based upon the foregoing or related risks we could incur significant costs relating to these claims. We maintain a \$5.0 million errors and omissions professional liability insurance policy to cover claims that may be brought against us. This coverage may not be adequate, or continue to be available in the future.

#### Patents and Trademarks

We hold registered service marks incorporating the DATATRAK® process, and trademarks, including the DATATRAK EDC™ software. The DATATRAK EDC™ software is the foundation of the DATATRAK® process. Intellectual property rights are significant to our continued operation and development.

## Employees

As of February 28, 2002, we had approximately 80 full-time employees. None of our employees are represented by a union, and we consider relations with our employees to be satisfactory. We do not have employment agreements with all of our executive officers. Due to the early stage of development of our industry and business, the loss of the services of any of our executive officers could put us at a competitive disadvantage, since we would need to attract a qualified new executive to fill the vacancy. To address these risks, we must, among other things, continue to attract, retain and motivate qualified personnel.

## ITEM 2. PROPERTIES

We presently lease approximately 14,000 square feet of space in Shaker Heights, a suburb of Cleveland, Ohio, of which approximately 6,000 square feet is sublet to an unrelated third party. The remaining 8,000 square feet are used to house our executive offices and our U.S. operations. This lease and sublease will both expire in April 2002. As a result, we have entered into a new lease for approximately 10,000 square feet of office space in Mayfield Heights, a suburb of Cleveland, Ohio. During 2002, we will relocate our executive offices and our U.S. operations to this new space.

We also lease, on a month-to-month basis, approximately 7,000 square feet of office space in Bonn, Germany for our European operations. We are currently exploring various options for the location of our European operations. These options include negotiating a long-term lease for the space we currently use or moving our European operations to a different location in or near Bonn, Germany.

## ITEM 3. LEGAL PROCEEDINGS

None.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At a special meeting of shareholders held on November 29, 2001, our shareholders voted to approve our private placement and to amend our Third Amended and Restated Code of Regulations.

The following is a summary of the voting:

<u>Votes</u>	<u>Approval of Private Placement</u>	<u>Amend the Code of Regulations</u>
For	1,708,665	1,729,310
Against	362,403	330,658
Abstain	300	11,400

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON SHARES AND RELATED SHAREHOLDER MATTERS

Our common shares are traded on The Nasdaq National Market ("Nasdaq") under the symbol "DATA." Our common shares were initially offered to the public on June 11, 1996 at a price of \$13.50 per share and commenced trading on Nasdaq on that date. The following table sets forth, for the fiscal years ended December 31, 2001 and 2000, the high and low sale prices per share for our common shares, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

	<u>High</u>	<u>Low</u>
<u>2001</u>		
First Quarter	\$ 4.06	\$ 2.56
Second Quarter	\$ 2.75	\$ 1.50
Third Quarter	\$ 3.40	\$ 1.21
Fourth Quarter	\$ 4.99	\$ 2.30
<u>2000</u>		
First Quarter	\$11.38	\$ 3.53
Second Quarter	\$ 7.13	\$ 3.75
Third Quarter	\$ 5.88	\$ 3.75
Fourth Quarter	\$ 4.88	\$ 2.13

On February 28, 2002, the last sale price of our common shares as reported by Nasdaq was \$3.30 per share. As of February 28, 2002, we had 78 shareholders of record.

We have never declared or paid cash dividends on our common shares. Any determination to pay cash dividends in the future will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, results of operations, current and anticipated cash needs and plans for expansion.

## ITEM 6.

## SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2001	2000	1999	1998	1997
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenue	\$ 2,246	\$ 1,994	\$ 5,811	\$ 13,226	\$ 17,327
Direct costs	1,780	1,597	3,763	10,511	12,637
Gross profit	466	397	2,048	2,715	4,690
Selling, general and administrative expenses	7,210	5,726	5,871	8,969	10,009
Impairment charge	----	----	----	6,056	----
Special items	----	----	----	1,998	2,995
Depreciation and amortization	949	867	800	1,155	1,015
Loss from operations	(7,693)	(6,196)	(4,623)	(15,463)	(9,329)
Other income, net	339	912	14,727	1,467	1,888
Income (loss) before income taxes	(7,354)	(5,284)	10,104	(13,996)	(7,441)
Income tax expense (benefit)	----	----	384	80	(58)
Net income (loss)	\$ (7,354)	\$ (5,284)	\$ 9,720	\$ (14,076)	\$ (7,383)
Net income (loss) per share: basic	\$ (2.23)	\$ (1.61)	\$ 1.87	\$ (2.19)	\$ (1.16)
Shares used in the computation of basic net income (loss) per share	3,291	3,290	5,209	6,422	6,384
Net income (loss) per share: diluted	\$ (2.23)	\$ (1.61)	\$ 1.84	\$ (2.19)	\$ (1.16)
Shares used in the computation of diluted net income (loss) per share	3,291	3,290	5,293	6,422	6,384

	December 31,				
	2001	2000	1999	1998	1997
	(In thousands, except per share data)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 5,204	\$ 12,040	\$ 17,536	\$ 26,693	\$ 33,613
Working capital	4,291	11,645	16,983	24,489	33,021
Total assets	7,634	14,486	19,483	33,540	48,321
Long-term liabilities	162	---	---	---	---
Accumulated deficit	(24,341)	(16,987)	(11,703)	(21,423)	(7,347)
Total shareholders' equity	5,755	13,104	18,306	28,238	42,350
Book value per common share	\$ 1.75	\$ 3.98	\$ 5.56	\$ 4.40	\$ 6.60
Cash dividends declared	---	---	---	---	---

The selected financial data presented above includes the operating results of our Clinical Business for all periods presented prior to April 20, 1999. Prior to April 20, 1999, the date we sold our Clinical Business, substantially all of our revenue and operating results were derived from the Clinical Business.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### General

We are an ASP that provides EDC and other services to companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industries. We assist our customers in accelerating the completion of clinical trials by streamlining the collection of data relating to clinical trials, and improving the overall quality of the clinical trial data collected. Through our Clinical Business, which we sold in

1999, we operated a multi-specialty site management organization that provided clinical research services to various clinical trial sponsors.

The discussion that follows highlights our business conditions and certain financial information. This discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Approximately 68% of our assets, or approximately \$5.2 million, are held in cash, cash equivalents and short-term investments. We have recognized little EDC revenue to date and have experienced significant losses and negative cash flow from operations. We are continuing to develop and commercialize our business, and anticipate that our operating results will fluctuate significantly from period to period.

We use a technology platform that consists of Windows™ compatible software and intranet hardware known as DATATRAK EDC™ to provide EDC and other services to clinical trial sponsors and CROs. Our future success is dependent on market acceptance of EDC in general, as an alternative to the traditional paper method of collecting clinical trial data, and acceptance of DATATRAK EDC™ specifically. We may be unsuccessful in achieving commercial acceptance of the DATATRAK® process.

Our contracts with our customers provide a fixed price for each component or service to be delivered, and we recognize revenue as these components or services are delivered. Services provided by us that are in addition to those provided for in our contracts are billed on a fee-for-service basis as completed. Generally, these contracts range in duration from one to three years. The ultimate contract value is dependent upon the length of the customer's use of DATATRAK EDC™ and the services we provide. As services are performed over the life of the contract, we recognize revenue per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Our customers, with or without cause, can terminate a contract at any time. If one of our contracts is cancelled, we are entitled to payment for all work performed through the date of notice of termination and for recovery of some or all costs incurred to terminate a contract. The termination of a contract will not result in a material adjustment to the revenue or costs we have previously recognized.

Since our purchase of the DATATRAK EDC™ software in January 1998, we have recorded revenue related to a small number of contracts. At December 31, 2001, our backlog was \$11.9 million. Backlog includes a \$2.4 million contract which is currently on hold. In the future, we may also record revenue related to the sales and licensing of software. Due to our early stage of development and low level of backlog, we may continue to recognize low levels of revenue.

#### Critical Accounting Policies

In response to the SEC's Release No. 33-8040, "Cautionary Advice Regarding Disclosure About Critical Accounting Policies," we have identified the most critical accounting principles upon which our financial status depends. Critical principles were determined by considering accounting policies that involve the most complex or subjective decisions or assessments. The most critical accounting policies were identified to be those related to revenue recognition and software development costs. Our revenue recognition and software development cost policies are stated in the notes to the consolidated financial statements and at relevant sections in this discussion and analysis.

#### Results of EDC Operations

During 2001, 2000 and 1999 we have recorded net operating losses from our EDC operations of \$7.7 million, \$6.2 million and \$4.9 million. During these years, our revenue has grown from \$900,000 in 1999 to \$2.0 million in 2000 to \$2.2 million in 2001. Our low level and slow growth of revenue are due to our low level of backlog, the slow growth of the EDC market, and the slow conversion of our backlog into revenue. During these three years our operating expenses have continued to increase from \$5.8 million in 1999, to \$8.2 million in 2000 and to \$9.9 million in 2001. Our personnel costs, which have represented approximately 40.0% to 50.0% of our operating expenses, have increased from \$2.1 million in 1999, to

\$3.6 million in 2000 and to \$5.2 million in 2001. This increase in personnel costs is a result of the growth in our sales, operations and software development staffs. We believe these increases in staff are necessary in order to continue to enhance our software offering, grow backlog and convert backlog into revenue. At December 31, 2001 we had approximately 75 employees.

At our current levels of revenue and conversion of backlog into revenue, we anticipate that our operating loss will be reduced during 2002. However, we anticipate that we will still record a net operating loss for the year ended December 31, 2002.

The following table shows, for the periods indicated, selected items from our Consolidated Statements of Operations, expressed as a percentage of revenue. Results for 1999 include only the results of our EDC operations.

	Year Ended December 31,		
	2001	2000	1999
Revenue	100.0%	100.0%	100.0%
Direct costs	79.3	80.1	85.1
Gross profit	20.7	19.9	14.9
Selling, general and administrative expenses	321.0	287.2	486.8
Depreciation and amortization	42.3	43.5	74.6
Loss from operations	(342.6)	(310.8)	(546.5)
Other income, net	15.1	45.7	285.8
Income (loss) before income taxes	(327.5)	(265.1)	(260.7)
Income tax expense	---	---	---
Net income (loss)	(327.5)	(265.1)	(260.7)

*Year ended December 31, 2001 compared with year ended December 31, 2000*

Revenue for the year ended December 31, 2001 increased by 10.0% to \$2.2 million, compared to \$2.0 million for the year ended December 31, 2000. The low level of growth was due to the slower than expected development and conversion of our backlog into revenue during 2001. During the second half of 2001, we began reorganizing our sales force and are continuing to increase our sales and marketing staff in order to attract new business and grow backlog.

Direct costs of revenue, mainly personnel costs, were \$1.8 million and \$1.6 million during the years ended December 31, 2001 and 2000. Our gross profit was \$470,000 and \$400,000 during 2001 and 2000. The 12.5% increase in direct costs was mainly the result of increased personnel costs of \$260,000 from the addition of new employees. The increase in personnel costs was partially offset by an \$80,000 decrease in other direct costs, mainly travel expenses and other costs, which are billed to our customers.

Selling, general and administrative ("SG&A") expenses include all administrative personnel costs, business and software development costs, and all other expenses not directly chargeable to a specific contract. These expenses increased by 26.3% to \$7.2 million from \$5.7 million for the years ended December 31, 2001 and 2000. The increase was primarily due to increased personnel costs of \$1.3 million caused by an increase in sales and marketing and software development personnel.

Depreciation and amortization expense increased to \$950,000 during the year ended December 31, 2001, from \$870,000 during the year ended December 31, 2000. The increase was the result of depreciating capital expenditures associated with the development of our information technology infrastructure.

Other income for the year ended December 31, 2001 totaled \$340,000, compared to \$910,000 for the year ended December 31, 2000. Other income includes interest income, which decreased \$510,000 for the year ended December 31, 2001 compared to December 31, 2000, due to our use of cash to fund operating losses and other working capital needs, and decreasing interest rates on our short-term

investments. For the year ended December 31, 2001, there was a \$50,000 decrease in foreign currency transaction adjustments compared to the year ended December 31, 2000.

Due to our loss for the year ended December 31, 2001, no income tax expense was recorded. At December 31, 2001 we had a net operating loss carryforward of approximately \$17.2 million, for United States income tax purposes, which will expire through the year 2021. We also had a net operating loss carryforward of approximately \$4.4 million, for German income tax purposes, with no expiration date. We have fully provided for our deferred tax assets through a valuation allowance.

*Year ended December 31, 2000 compared with year ended December 31, 1999*

Revenue for the year ended December 31, 2000 increased by 122.2% to \$2.0 million, compared to \$900,000 for the year ended December 31, 1999. Of this increase, \$900,000 is from customers with which we established relationships in 1999 and the remainder of the increase results from contracts with new customers.

Direct costs of revenue, mainly personnel costs, were \$1.6 million and \$770,000 during the years ended December 31, 2000 and 1999. Our gross profit was \$400,000 and \$130,000 during 2000 and 1999. The 107.8% increase in direct costs was mainly the result of increased personnel costs of \$640,000 from the addition of new employees. The remaining increase was due to additional contract costs related to the increased usage of the DATATRAK EDC™ software. During 2000, we completed an analysis of employee and other costs relating to research and development activities. Such research and development costs for 1999, totaling \$260,000 were reclassified from direct costs to SG&A expenses to conform to the 2000 reporting presentation.

SG&A expenses increased by 29.6% to \$5.7 million from \$4.4 million for the years ended December 31, 2000 and 1999. The increase was primarily due to increased personnel costs of \$930,000. Included in the \$930,000 increase in personnel costs is a one-time, non-cash charge of \$110,000 for compensation expense on stock options. These stock options have exercise prices below the market value of our common shares on the date the stock option plan relating to these stock options was approved by our shareholders. Other SG&A costs associated with our development and marketing efforts increased by \$350,000. A one-time expense of \$350,000 associated with services to assess the market potential of the DATATRAK EDC™ software is included in 1999 SG&A. The absence of this expense was offset by \$370,000 of additional consulting costs in 2000.

Depreciation and amortization expense increased to \$870,000 during the year ended December 31, 2000 from \$670,000 during the year ended December 31, 1999. The increase was the result of depreciating capital expenditures associated with the development of our information technology infrastructure.

Other income for the year ended December 31, 2000 totaled \$910,000, compared to \$2.6 million for the year ended December 31, 1999. During 1999, \$1.3 million was received as the result of a favorable outcome in a lawsuit. Other income also includes interest income which decreased \$430,000 in 2000, compared to the year ended December 31, 1999, due to our use of cash to fund our repurchase of common shares in August 1999, operating losses and other working capital needs.

Due to our loss for the year ended December 31, 2000, no income tax expense was recorded.

*Clinical Business Results of Operations*

From January 1, 1999 to April 20, 1999, we recorded operating results related to our Clinical Business. During this time period, the Clinical Business had revenue of \$4.9 million. Direct costs, SG&A and depreciation expenses totaled \$4.6 million resulting in income from operations of \$290,000. Our April 20, 1999 sale of the Clinical Business resulted in a gain of \$12.2 million. We incurred income tax expense of \$380,000 for the year ended December 31, 1999 as a result of federal alternative minimum taxes and state income taxes incurred related to the gain associated with the sale of the Clinical Business.



## Liquidity and Capital Resources

Our principal sources of cash have been cash flow from operations and proceeds from the sale of equity securities. The 1999 sale of our Clinical Business generated \$15.6 million in cash and we also received \$1.3 million in cash during 1999 from a favorable legal settlement. Our investing activities primarily reflect capital expenditures and net purchases of short-term investments. In 1999, we repurchased 3.3 million of our common shares at a cost of \$20.2 million. On January 7, 2002, we raised approximately \$4.0 million in cash with the completion of our private placement.

Contracts with our customers usually require a portion of the contract amount to be paid at the time the contract is initiated. Additional payments are generally received upon completion of negotiated performance milestones throughout the life of the contract. We record all amounts received as a liability (deferred revenue) until work has been completed and revenue is recognized. Cash receipts do not necessarily correspond to costs incurred or revenue recognized. We typically receive a low volume of large-dollar receipts. Our accounts receivable will fluctuate due to the timing and size of cash receipts. Accounts receivable (net of allowance for doubtful accounts) was \$430,000 at December 31, 2001 and \$610,000 at December 31, 2000. Deferred revenue was \$470,000 at December 31, 2001 and \$340,000 at December 31, 2000.

Cash and cash equivalents decreased \$210,000 during the year ended December 31, 2001. This was the result of \$6.2 million provided by investing activities, and \$6.4 million used by operating and financing activities. Investing activities included net proceeds of \$6.9 million from purchases and maturities of short-term investments offset by \$690,000 used to purchase property and equipment. A capital lease obligation of \$390,000, entered into during the year ended December 31, 2001, is excluded from financing and investing activities on our Condensed Consolidated Statement of Cash Flows. A total of \$120,000, including interest, was paid under the capital lease obligation during 2001. Cash used for operating activities resulted from the funding of net operating losses and other working capital needs.

At December 31, 2001, we had working capital of \$4.3 million, and our cash, cash equivalents and short-term investments totaled \$5.2 million. Our working capital has decreased by \$7.4 million since December 31, 2000. The decrease was primarily the result of a \$6.8 million decrease in our cash, cash equivalents and short-term investments and a \$310,000 decrease in accounts and other receivables.

We are responsible for funding the enhancement and testing of the DATATRAK EDC™ software. We will continue to invest in the development of the DATATRAK® process. Our operations and the EDC market are still in a developmental stage. We have experienced marginal revenue growth, however, we anticipate negative cash flow from operations during 2002 as we continue to build our operational and business development infrastructure. We anticipate capital and related expenditures of approximately \$1.6 million for the twelve months ending December 31, 2002 for the continued commercialization and enhancement of DATATRAK EDC™, which we expect to fund from existing cash and cash equivalents, maturities of short-term investments and cash flow from operations. We believe that, with the cash raised in our January 2002 private placement, our cash and cash equivalents, maturities of short-term investments and cash flow from operations, will be sufficient to meet our working capital and capital expenditure requirements through December 31, 2002. However, we may need to raise additional funds to support expansion, respond to competitive pressures, acquire complementary businesses or technology or take advantage of unanticipated opportunities. We may need to raise additional funds by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Additional capital may not be available on acceptable terms, if at all. To the extent that additional equity capital is raised, it could have a dilutive effect on our existing shareholders.

## Contractual Obligations

The table below shows our contractual cash obligations, expressed in thousands, at December 31, 2001.

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1 – 3 years	4 – 5 years	After 5 years
Capital lease obligations	\$ 314	\$ 145	\$ 169	\$ ---	\$ ---
Operating leases	1,584	188	390	423	583
Total contractual cash obligations	<u>\$1,898</u>	<u>\$ 333</u>	<u>\$ 559</u>	<u>\$ 423</u>	<u>\$ 583</u>

## Inflation

To date, we believe that the effects of inflation have not had a material adverse effect on our results of operations or financial condition.

## Interest Rate Risk

We have fixed income investments consisting of cash equivalents and short-term investments, which may be affected by changes in market interest rates. We do not use derivative financial instruments in our investment portfolio. We place our cash equivalents and short-term investments with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity. Investments are reported at amortized cost, which approximates fair value.

## Foreign Currency Risk

Our foreign sales and results of operations are subject to the impact of foreign currency fluctuations. Approximately 20% of our 2001 revenue was earned in Germany by our subsidiary, DATATRAK GmbH. We manage our risk to foreign currency exchange rates by maintaining foreign currency bank accounts in currencies in which we regularly transact business. We do not currently hedge against the risk of exchange rate fluctuations. On January 1, 2002, we began transacting business in Germany using Euros. The conversion to the Euro is not expected to have a material impact on our financial position, results of operations or cash flows.

## Information About Forward-Looking Statements

Certain statements made in this Annual Report on Form 10-K contain certain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934 ("Exchange Act"). All statements that address operating performance, events or developments that we anticipate will occur in the future, including statements related to future revenue, profits, expenses, income and earnings per share or statements expressing general optimism about future results, are forward-looking statements. In addition, words such as "expects," "anticipates," "intends," "plans," "believes," "estimates," variations of such words, and similar expressions are intended to identify forward-looking statements. Forward-looking statements are subject to the safe harbors created in the Exchange Act.

Forward-looking statements are subject to numerous assumptions and risks and uncertainties that may cause our actual results or performance to be materially different from any future results or performance expressed or implied by the forward-looking statements. We have identified the following important factors, which could cause our actual operational or financial results to differ materially from any projections, estimates, forecasts or other forward-looking statements made by or on our behalf. Under no

circumstances should the factors listed below be construed as an exhaustive list of all factors that could cause actual results to differ materially from those expressed in forward-looking statements. We undertake no obligation to review or confirm analysts' expectations or estimates or to release publicly any revisions to these forward-looking statements to take into account events or circumstances that occur after the date of this Annual Report on Form 10-K. In addition, we do not undertake any responsibility to update publicly the occurrence of unanticipated events, which may cause actual results to differ from those expressed or implied by these forward-looking statements.

**We have a limited operating history and we have not had profitable operations.**

We began providing EDC services in 1997 and have a limited operating history upon which investors may evaluate our performance. We have recognized operating losses in each year since 1997. Our cumulative operating loss since 1997 from EDC operations totaled \$31.9 million at December 31, 2001, and we may not be profitable during future periods.

**If we do not continue to enhance our software, we may not be able to meet the needs of our customers.**

Although the DATATRAK EDC™ software has been used in clinical trials, its continued enhancement is necessary to provide additional functionality and services to meet the ever-changing needs and expectations of our customers. Among the enhancements we have added to our software are features including electronic signatures, single user login for added security and multiple user access. To date we have had little EDC revenue from which to support the costs of this continued software enhancement. Our potential future revenue, may not be sufficient to absorb corporate overhead and other fixed operating costs that will be necessary for the success of the DATATRAK® process.

**Our quarterly results fluctuate significantly.**

We are subject to significant fluctuations in quarterly results caused by many factors, including our success in obtaining new contracts, the size and duration of the clinical trials in which we participate, the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials and other factors, which could cause our revenue predictions to be incorrect. Our expense levels are based in part on our expectations as to future revenue and to a certain extent are fixed. We may be unable to adjust expenses in a timely manner to compensate for any unexpected revenue shortfall. As a result of our relatively small revenue base, any significant shortfall in revenue recognized during a particular period could have an immediate adverse effect on our income from operations and financial condition. Volatility in our quarterly results may adversely affect the market price of our common shares.

**Our business strategies are unproven and we are in an early stage of development.**

Our efforts to establish a standardized EDC process for collection and management of clinical research data represent a significant departure from the traditional clinical research practices of clinical trial sponsors. The long-term viability of our business remains unproven. Our strategy may not gain acceptance among sponsors of clinical research, research sites or investigators. Our prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development, particularly companies in new and rapidly evolving markets.

**We may lose revenues if we experience delays in clinical trials or if we lose contracts.**

Although our contracts provide that we are entitled to receive revenue earned through the date of termination, our customers generally are free to delay or terminate a clinical trial or our contract related thereto at any time. The length of a typical clinical trial contract varies from several months to several years. Clinical trial sponsors may delay or terminate clinical trials for several reasons, including unexpected results or adverse patient reactions to a potential product, inadequate patient enrollment or investigator recruitment, manufacturing problems resulting in shortages of a potential product or decisions by the sponsor to de-emphasize or terminate a particular trial or drug. Because of our low level of backlog

and revenue, we may lose revenues if a clinical trial sponsor decides to delay or terminate a trial in which we participate.

We may lose revenues if any of our customers decrease their research and development expenditures, or if we lose any of our major customers.

Our primary customers are companies in the pharmaceutical industry. Our business depends on the research and development expenditures of companies in this industry. During 2001 and 2000, Quintiles, Inc. accounted for 11% and 52% of our revenue, and Aventis Pharmaceuticals, Inc. accounted for 22% and 27% of our revenue. Furthermore, during 2001, Control Delivery Systems, Inc. and CV Therapeutics, Inc. accounted for 23% and 21% of our revenue. The extent to which we rely on revenue from one customer varies from period to period, depending upon, among other things, our ability to generate new business, the timing and size of clinical trials and other factors. In light of our small revenue base, we are more dependent on major customers than many of the larger participants in the EDC industry. Our operations could be materially and adversely affected by, among other things, any economic downturn or consolidations in the pharmaceutical or biotechnology industries, any decrease in their research and development expenditures or a change in the regulatory environment in which these companies operate.

Changes in government regulations relating to the health care industry could have a material adverse effect on the demand for our services.

Demand for our services is largely a function of the regulatory requirements associated with the approval of a New Drug Application by the FDA. These requirements are more stringent and thus more burdensome than those imposed by many other developed countries. In recent years, efforts have been made to streamline the drug approval process and coordinate U.S. standards with those of other developed countries. Changes in the level of regulation, including a relaxation in regulatory requirements or the introduction of simplified drug approval procedures could have a material adverse effect on the demand for our services. Several competing proposals to reform the system of health care delivery in the United States have been considered by Congress from time to time. None of the proposals have been adopted.

The FDA's guidelines and rules related to the use of computerized systems in clinical trials are still in the early stages of development. We cannot assure you that the DATATRAK® process can be kept in compliance with these guidelines and rules as they develop. Any release of FDA guidance that is significantly inconsistent with the design of DATATRAK EDC™ may cause us to incur substantial costs to remain in compliance with FDA guidance and regulations.

We may not be able to capture or establish the market presence necessary to compete in the EDC market.

The EDC market, which is still developing, and must compete with the traditional paper method of collecting clinical trial data, is highly fragmented. The major competitors, in the EDC market, include EDC software vendors, clinical trial data service companies and in-house development efforts within large pharmaceutical companies. Any current and potential future competitors have or may have substantially greater resources, greater name recognition and more extensive customer bases that could be leveraged, thereby gaining market share or product acceptance to our detriment.

We may be subject to liability for potential breaches of contracts or losses relating to the unauthorized release of clinical trial data.

Our services are supported by telecommunications equipment, software, operating protocols and proprietary applications for high-speed transmission of large quantities of data among multiple locations. In addition, clinical pharmaceutical and medical device research requires the review and handling of large amounts of patient data. Potential liability may arise from a breach of contract or a loss of or unauthorized release of clinical trial data. Our financial position could be materially adversely affected if we were forced to undertake the defense of, or were found financially responsible for, claims based upon the foregoing or related risks. We maintain a \$5.0 million errors and omissions professional liability insurance policy to cover

claims that may be brought against us. This coverage may not be adequate, or continue to be available to us, in the future.

**We have provisions that may prevent a third-party acquisition and allow us to issue preferred shares.**

Our Articles of Incorporation and By-Laws contain provisions that may discourage a third party from acquiring, or attempting to acquire us. These provisions could limit the price that certain investors might be willing to pay for our common shares. In addition, our Board of Directors, without shareholder approval, can issue preferred shares whether under our shareholder rights plan or for other uses as determined by our Board. The issuance of preferred shares may adversely affect the rights of common shareholders, the market price of our common shares and may make it more difficult for a third party to acquire a majority of our outstanding common shares. At the present time, we do not plan to issue any preferred shares.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risk from changes in interest rates and foreign currency exchange rates since we fund our operations through long-and short-term investments and have business transactions in German Deutschmarks. A summary of our primary market risk exposures is presented below.

##### **Interest Rate Risk**

We have fixed income investments consisting of cash equivalents and short-term investments, which may be affected by changes in market interest rates. We do not use derivative financial instruments in our investment portfolio. We place our cash equivalents and short-term investments with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity. Investments are reported at amortized cost, which approximates fair value. A 1.0% change in interest rates during the year ended December 31, 2001, would have resulted in an \$86,000 change in our interest income during the year.

##### **Foreign Currency Risk**

Our foreign sales and results of operations are subject to the impact of foreign currency fluctuations. Approximately 20% of our 2001 revenue was earned in Germany by our subsidiary, DATATRAK GmbH. We manage our risk to foreign currency exchange rates by maintaining foreign currency bank accounts in currencies in which we regularly transacts business. We do not currently hedge against the risk of exchange rate fluctuations. A 1.0% fluctuation in the exchange rate between United States dollars and German Deutschmarks at December 31, 2001, would have resulted in a \$16,000 change in the foreign currency translation amount recorded on our balance sheet and had a negligible effect on our net income.

On January 1, 2002, we began transacting business in Germany using Euros. The conversion to the Euro is not expected to have a material impact on our financial position, results of operations or cash flows.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Quarterly results of operations for the year ended December 31, 2001 are included in Note 15 of the Consolidated Financial Statements.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The name, age and positions of each of our directors and executive officers are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Dr. Jeffrey A. Green (1)	46	President, Chief Executive Officer and Director
Terry C. Black	44	Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary
Marc J. Shlaes	47	Vice President of Research and Development
Dr. Wolfgang Summa	37	Vice President of Global Operations
Mark J. Levine	56	Executive Vice President of Global Business Development
Timothy J. Biro (1) (3)	48	Director
Dr. Robert M. Stote (2)	62	Director
Jerome H. Kaiser (3)	44	Director
Dr. Mark J. Ratain (3)	47	Director
Seth B. Harris (2)	61	Director
Robert E. Flaherty (1) (2)	55	Director

(1) Member of the Executive Committee.

(2) Member of the Compensation Committee.

(3) Member of the Audit Committee.

Jeffrey A. Green, Pharm.D., FCP, is our founder and has served as our President, Chief Executive Officer and a Director since March 1992. From 1984 to 1992, Dr. Green served as an Assistant Professor of Medicine and Radiology at Case Western Reserve University, Cleveland, Ohio. During his tenure at Case Western Reserve University, Dr. Green established and directed the Cardiovascular Clinical Pharmacology Research Program at University Hospitals of Cleveland. In addition, Dr. Green was an established investigator in clinical cardiology and PET scanning, and was responsible for directing over 90 individual investigations during his tenure. Dr. Green has authored over 90 publications and has been an invited speaker at more than 170 national meetings. He was the recipient of the McKen Cattell Distinguished Achievement Award from the American College of Clinical Pharmacology in 1988. Dr. Green is a graduate of Purdue University (B.S.) and the University of Texas (Pharm.D.).

Terry C. Black, MBA, CPA, has served as our Vice President of Finance and Chief Financial Officer since June 1994 and has served as our Treasurer and Assistant Secretary since January 1996. Prior to joining us, Mr. Black served in a variety of financial and accounting positions within the insurance replacement rental car industry.

Marc J. Shlaes, BB, has served as our Vice President of Research and Development since December 2000. Mr. Shlaes is responsible for the development and testing of DATATRAK EDC™ and our related software offerings. From October 1999 through December 2000, Mr. Shlaes served as our Vice President and Managing Director of North America. Prior to his appointment as Vice President and Managing Director of North America, Mr. Shlaes served as our Director of Technology and Services. Prior to joining us in 1998, Mr. Shlaes served in a variety of positions in the software development and delivery industry, including as an employee of International Business Machines from 1982 to 1996.

Wolfgang Summa, PhD., MSc., has served as our Vice President of Global Operations since December 2000. Dr. Summa is responsible for our operational strategy including the delivery of DATATRAK EDC™ to customers as well as the management of our clinical trials. From October 1999 through December 2000, Dr. Summa served as our Vice President and Managing Director of Europe. From January 1998 to October 1999, Dr. Summa served as our Manager of European Operations. Prior to joining us, Dr. Summa served in various research positions for PadCom Clinical Research and Electronic Data Systems. Dr. Summa is a graduate of the University of Bonn (MSc., PhD.).

Mark J. Levine has served as our Executive Vice President of Global Business Development since August 2001. Mr. Levine is responsible for developing our marketing strategy and building and developing our international sales force. From 1999 until joining us, Mr. Levine was Director, Account Management for Quintiles, Inc. From 1996 until 1999, Mr. Levine was Director, Business Development for Clintrials Research, Inc. Throughout his thirty plus year career, Mr. Levine has served in various capacities for several companies in the pharmaceutical industry.

Mark J. Ratain, M.D., has been a Director since April 1998. Dr. Ratain is a hematologist/oncologist and a clinical pharmacologist. He is a Professor of Medicine, Chairman of the Committee on Clinical Pharmacology and Pharmacogenomics, and Associate Director for Clinical Sciences of the Cancer Research Center at the University of Chicago. Dr. Ratain has been associated with the Department of Medicine at the University of Chicago since 1983.

Seth B. Harris has been a Director since 1992 and has been the Chairman of Freider the Source, a distributor of consumer products, since 1993. Mr. Harris is also a Director of Bindley Western Industries, Inc. (New York Stock Exchange, "BDY"), one of the largest distributors of pharmaceuticals in the United States.

Robert E. Flaherty has been a Director since July 1998. Mr. Flaherty has been the President and Chief Executive Officer of Athena Diagnostics, Inc., a unit of the Elan Pharmaceuticals division of Elan Corporation, plc. since 1992. Elan Pharmaceuticals is involved in the discovery, development and marketing of therapeutic agents for the diagnosis and treatment of central nervous system diseases and disorders.

Timothy G. Biro, MBA, has been a Director since 1992. Mr. Biro has been the Managing Partner of Ohio Innovation Fund I, L.P., a venture capital firm since 1997. Mr. Biro has also been a Superintendent of Pharmaceutical Manufacturing at Merck & Co., Inc.

Robert M. Stote, M.D., Dr. has been a Director since 1993. Dr. Stote has served as the Senior Vice President and Chief Science Officer and a Director of Bentley Pharmaceuticals, Inc., a pharmaceutical company since 1992.

Jerome H. Kaiser, Ph.D., has been a Director since December 1999. Dr. Kaiser is the Senior Vice President and Director of Information Services for Rothschild, Inc., a private investment bank. During 1998 and 1999, he was the Director of Product Management for Pfizer, Inc. From 1994 to 1998, Dr. Kaiser was employed by Hoffman-LaRoche, Inc.

#### Terms of Directors

The number of Directors is currently fixed at seven. The Board of Directors is divided into two classes. The term of one class of Directors expires each year as follows: (1) Dr. Ratain and Messrs. Flaherty and Harris will serve until the 2002 annual meeting and (2) Messrs. Biro and Kaiser and Drs. Stote and Green will serve until the 2003 annual meeting.

#### Committees of the Board of Directors

The Board of Directors has three standing committees: an Executive Committee, a Compensation Committee and an Audit Committee. The Executive Committee has the authority to exercise all powers of the Board of Directors at any time when the entire Board of Directors cannot meet.

The Compensation Committee has the authority to administer our stock option plans, including the selection of optionees and the timing of option grants, and review and monitor key employee compensation and benefits policies and administer our management compensation plans.

The Audit Committee recommends the annual appointment of our auditors, with whom the Audit Committee reviews the scope of audit and non-audit assignments and related fees, the accounting principles used by us in financial reporting, internal financial auditing procedures and the adequacy of our internal control procedures.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our Directors and certain of our executive officers and persons who beneficially own more than 10% of our common shares to file reports of ownership and changes in ownership on Forms 3, 4 and 5 with the Securities and Exchange Commission (the "Commission") and Nasdaq. These people are further required to furnish us with copies of all such forms filed by them. Based solely on our review of the copies of the forms we have received, we believe that all of the Section 16(a) filing requirements were satisfied by our Directors, executive officers and beneficial owners of more than 10% of the our common shares, except for a report relating to Mr. Harris's purchase of a total of 5,500 of our common shares, which took place between August 28 and August 31, 2001.

### ITEM 11. EXECUTIVE COMPENSATION

#### Compensation of Directors

Our Directors do not receive cash compensation for their service on our Board of Directors. However, they do receive reimbursement for reasonable expenses incurred in attending meetings of the Board of Directors. Directors who are not employees receive options to purchase common shares under our 1999 Outside Director Stock Option Plan (the "1999 Director Plan"). Under the terms of this plan, each non-employee Director receives (1) an initial option grant to purchase 10,000 common shares at an exercise price equal to the fair market value of a share on the date of grant and (2) an annual option grant to



purchase 12,500 common shares at an exercise price equal to the fair market value of a share on the date of grant. The annual grant occurs automatically on the day of our annual shareholder meeting. As of December 31, 2001, options to purchase an aggregate of 222,500 common shares had been awarded under the 1999 Director Plan at exercise prices ranging from \$2.00 to \$5.19 per share.

After our initial public offering, non-employee Directors received options to purchase common shares under our Amended and Restated 1996 Outside Directors' Stock Option Plan, as amended (the "1996 Director Plan"). Under the terms of the 1996 Director Plan, each non-employee Director received an annual option grant to purchase 1,500 common shares at an exercise price equal to the fair market value of a share on the date of grant. As of December 31, 2001, options to purchase an aggregate of 66,500 common shares were outstanding under the 1996 Director Plan at exercise prices ranging from \$4.19 to \$9.60 per share.

Prior to our initial public offering, Directors received options under other option plans. Non-employee Directors received options to purchase common shares under our Amended and Restated 1992 Share Incentive Plan (the "1992 Plan"). Options to purchase an aggregate of 80,000 common shares were awarded to non-employee Directors under the 1992 Plan at an exercise price of \$0.15 per share. Each Director who is not a Named Executive Officer received options to purchase the following numbers of common shares under the 1992 Plan: Mr. Harris, 25,000 common shares; Dr. Stote, 25,000 common shares; and Dr. Ratain, 30,000 common shares. Dr. Ratain was awarded stock options for his service as a consultant prior to becoming a Director. In addition, prior to our initial public offering, Directors who were designated by certain investors received, in lieu of Directors' fees, options to purchase common shares having a value equal to \$1,000 for each meeting attended (\$500 for each meeting attended by telephone). These awards were made under our Amended and Restated 1994 Directors' Share Option Plan (the "Director Plan"). An aggregate of 6,667 options are outstanding under the Director Plan at exercise prices ranging from \$0.80 to \$9.60 per share.

#### Executive Officer Compensation

The table below sets forth certain information concerning the annual or long-term compensation for services in all capacities to during the fiscal years ended December 31, 2001, 2000 and 1999 to our Chief Executive Officer and our three other highest paid executive officers whose annual salary and bonus exceeded \$100,000 (the "Named Executive Officers").

Name and Principal Position	Year	Summary Compensation		Long-Term Compensation Awards	
		Annual Compensation (1)		Securities Underlying Options/SARs	All Other Compensation (2)
		Salary	Bonus		
Dr. Jeffrey A. Green .....	2001	\$180,000	\$ ---	---	\$---
President, Chief Executive	2000	180,000	---	---	---
Officer and Director	1999	180,000	---	90,000(3)	---
Terry C. Black .....	2001	125,000	---	---	---
Vice President of Finance, Chief	2000	125,000	---	---	---
Financial Officer, Treasurer and	1999	125,000	10,000	31,250(4)	---
Assistant Secretary					
Marc J. Shlaes .....	2001	110,000	---	---	---
Vice President of Research	2000	110,000	---	---	---
and Development	1999	107,000	30,000	57,500(5)	---
Dr. Wolfgang Summa .....	2001	96,264(6)	7,330	---	---
Vice President of Global	2000	93,657	---	---	---
Operations	1999	86,236	33,000	57,500(7)	---

- (1) No Named Executive Officer received perquisites or other personal benefits in excess of the lesser of \$50,000 or 10% of that individual's salary plus annual bonus. No long-term incentive plan payouts or restricted stock awards have been made to any of the Named Executive Officers.
- (2) No other compensation was received by the Named Executive Officers.
- (3) Dr. Green's options were granted on December 9, 1999, at an exercise price of \$3.63 per share, 50% of which became exercisable on December 9, 2001 and 50% of which will become exercisable on December 9, 2003.
- (4) Mr. Black's options were granted on December 9, 1999, at an exercise price of \$3.63 per share, 50% of which became exercisable on December 9, 2001 and 50% of which will become exercisable on December 9, 2003.
- (5) Mr. Shlaes's options were granted as follows: (1) 30,000 on September 22, 1999, at an exercise price of \$3.75 per share, 25% of which became exercisable on each of September 22, 2000, September 22, 2001, and 25% of which will become exercisable on each of September 22, 2002 and September 22, 2003 and (2) 27,500 on December 9, 1999, at an exercise price of \$3.63 per share, 50% of which became exercisable on December 9, 2001 and 50% of which will become exercisable on December 9, 2003.
- (6) Dr. Summa's current employment contract provides for a base salary of DM 210,000 (German Deutschmarks), which is intended to approximate \$110,000. Based on the average exchange rate between the United States dollar and the German Deutschmark during 2001, Dr. Summa's salary in 2001 of DM 210,000 was the equivalent of \$96,264.
- (7) Dr. Summa's options were granted as follows: (1) 30,000 on September 22, 1999, at an exercise price of \$3.75 per share, 25% of which became exercisable on each of September 22, 2000, September 22, 2001, and 25% of which will become exercisable on each of September 22, 2002 and September 22, 2003 and (2) 27,500 on December 9, 1999, at an exercise price of \$3.63 per share, 50% of which became exercisable on December 9, 2001 and 50% of which will become exercisable on December 9, 2003.

#### Option Grants

No stock options were granted to the Named Executive Officers during the year ended December 31, 2001.

#### Option Exercises and Fiscal Year-End Option Values

The table below shows information with respect to the exercise of options to purchase common shares by the Named Executive Officers and unexercised options to purchase common shares for the Named Executive Officers as of December 31, 2001.

Aggregate Option Exercises in Last Fiscal Year  
And December 31, 2001 Option Value

Name	Stock Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at December 31, 2001		Value of Unexercised In-the-Money Options at December 31, 2001(1)	
			Exercisable	Unexercisable	Exercisable(2)	Unexercisable
Dr. Jeffrey A. Green .....	---	\$ ---	95,000	45,000	\$ ---	\$ ---
Terry C. Black .....	---	---	50,625	15,625	25,000	---
Marc J. Shlaes.....	---	---	40,750	28,750	---	---
Dr. Wolfgang Summa....	---	---	28,750	28,750	---	---

- (1) Options are in-the-money if the market value of our common shares exceeds the exercise price.
- (2) Represents the total gain which would be realized if all in-the-money options beneficially held at December 31, 2001 were exercised, determined by multiplying the number of common shares underlying the options by the difference between the per share option exercise price and \$2.65, the closing price for our common shares as reported by Nasdaq on December 31, 2001.

### Employment Agreements

*Dr. Jeffrey A. Green.* In February 2001, we entered into an employment agreement with Dr. Green providing for an initial term of one year. This agreement will automatically renew for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary provided for in this agreement is \$180,000 per year, to be reviewed at least annually by the Compensation Committee. Bonuses may be paid to Dr. Green at the discretion of the Compensation Committee. The agreement also provides Dr. Green with the right to participate in all benefit plans made available to our executives and/or employees. Dr. Green's employment may be terminated with or without cause, upon his death or disability or with sufficient reason. Additionally, under this agreement, Dr. Green is entitled to terminate his employment for "good reason." "Good reason" for such termination will exist if at any time, (1) there is a material breach of Dr. Green's employment agreement by us, (2) our shareholders fail to elect Dr. Green to the Board of Directors or Dr. Green is otherwise removed from the Board of Directors, and (3) except in connection with the termination of Dr. Green's employment in strict compliance with the terms of the agreement, the Board of Directors (a) fails to elect Dr. Green to his current executive position, (b) fails to vest Dr. Green with the powers and authority customarily associated with his current position or (c) significantly diminishes his responsibilities, duties, power or authority. If Dr. Green terminates his employment for good reason, he will be entitled to continue to receive his base salary for two years following the date of such termination. If Dr. Green's employment is terminated in connection with the sale of our company, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause or without sufficient reason, he will be entitled to continue to receive his base salary for a period of two years subsequent to the date of termination. If Dr. Green terminates his employment without good reason, or if he is terminated for "cause," then he will be entitled to receive his base salary through the date of termination. For purposes of Dr. Green's agreement, "cause" is defined as a determination by the Board of Directors that the employee was (1) convicted of a felony involving moral turpitude or a felony in connection with his employment, (2) engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (3) using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (4) engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on our reputation or business. "Sufficient reason" shall mean a good faith determination that the employee failed to adequately perform his duties as an officer or achieve the business objectives mutually agreed upon by the parties. Dr. Green also agreed to certain noncompetition and nondisclosure provisions, which under certain conditions continue for a period of up to twenty-four months following a termination of Dr. Green's employment.

*Terry C. Black.* In February 2001, we entered into an employment agreement with Mr. Black providing for an initial term of one year. This agreement will automatically renew for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary initially provided for in this agreement is \$125,000 per year, to be reviewed at least annually by the Compensation Committee. Bonuses may be paid to Mr. Black at the discretion of the Compensation Committee. The agreement also provides Mr. Black with the right to participate in all benefits plans made available to our executives and/or employees. Mr. Black's employment with us may be terminated with or without cause or upon his death or disability. Additionally, Mr. Black is entitled to terminate his employment for "good reason." If Mr. Black terminates his employment for good reason, he will be entitled to receive his base salary for a period of one year following the date of such termination. If Mr. Black's employment is terminated in connection with the sale of our company, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause, he will be entitled to receive his base salary for a period of one year subsequent to the date of termination. If Mr. Black terminates his employment without good reason, or if he is terminated for "cause," he will be

entitled to receive his base salary through the date of termination. For purposes of Mr. Black's agreement, "cause" is defined as a determination by the Board of Directors that the employee was (1) convicted of a felony involving moral turpitude or a felony in connection with his employment, (2) engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (3) using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (4) engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on our reputation or business. Mr. Black also agreed to certain noncompetition and nondisclosure provisions, which continue under certain conditions for a period up to eighteen months following a termination of Mr. Black's employment.

*Dr. Wolfgang Summa.* In December 2000, Dr. Summa signed an employment agreement with our wholly owned subsidiary, DATATRAK Deutschland GmbH, providing for an initial term of four years. This agreement will automatically renew for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary initially provided for in this agreement is DM 210,000 (approximately \$110,000) per year, to be reviewed at least annually by the Compensation Committee. Bonuses may be paid to Dr. Summa at the discretion of the Compensation Committee. The agreement also provides Dr. Summa with the right to participate in all benefits plans made available to our executives and/or employees. Dr. Summa's employment may be terminated with or without cause or upon his death or disability. Additionally, Dr. Summa is entitled to terminate his employment for "good reason." If Dr. Summa terminates his employment for good reason, he will be entitled to receive his base salary for a period of one year following the date of such termination. If Dr. Summa's employment is terminated in connection with the sale of our company, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause, he will be entitled to receive his base salary for a period of one year subsequent to the date of termination. If Dr. Summa terminates his employment without good reason, or if he is terminated for "cause," he will be entitled to receive his base salary through the date of termination. For purposes of Dr. Summa's agreement, "cause" is defined as a determination by the Board of Directors that the employee was (1) convicted of a felony involving moral turpitude or a felony in connection with his employment, (2) engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (3) using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (4) engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on our reputation or business. Dr. Summa also agreed to certain noncompetition and nondisclosure provisions, which continue under certain conditions for a period up to eighteen months following a termination of Dr. Summa's employment. The agreement is governed by German law.

#### Compensation Committee Interlocks and Insider Participation

We have engaged in various private transactions with the members of our Compensation Committee or entities with which they are affiliated. We believe that these transactions have been on terms no less favorable to us than could have been obtained from unaffiliated third parties.

We engaged in various private equity financing transactions with Mr. Harris, Dr. Stote and other shareholders in 1992, 1993 and 1994. As a result of those transactions, Mr. Harris and Dr. Stote are among the parties to a registration rights agreement with us, under which they have been provided certain rights to have their common shares registered under the Securities Act of 1933, as amended (the "Securities Act").

#### Compensation Committee Report on Executive Compensation

*General.* The Compensation Committee administers our stock option plans, including the selection of optionees and the timing of option grants, reviews and monitors key employee compensation and benefits policies and administers our management compensation plans. The current members of the Compensation Committee are Messrs. Flaherty and Harris and Dr. Stote, all of whom are non-employee Directors.

This report contains a discussion of our compensation philosophy, together with a discussion of the factors considered by the Compensation Committee in determining the compensation of our President and Chief Executive Officer and the Named Executive Officers.

*Compensation Philosophy.* Our compensation philosophy is that compensation paid to executive officers and other management personnel should consist of four elements: (1) salary, (2) annual incentive bonus, (3) stock options and (4) welfare, retirement and other benefits. The compensation package is designed to attract and retain top quality management employees. To some extent, elements of compensation are designed to vary as our performance varies. In general, the elements of compensation that most typically have a significant relationship to our performance are awards under our stock option and bonus plans. The Compensation Committee's decisions concerning compensation make use of independent surveys of executive compensation of similarly situated companies.

Presented below is a discussion of the various components of the compensation arrangements provided to the Named Executive Officers, as well as a discussion of the compensation arrangements provided to our President and Chief Executive Officer.

#### *2001 Compensation Decisions*

*Base Salary and Benefits.* Salaries of executive officers are subject to minimum levels set by the terms of each executive's employment arrangement or other arrangements with the executive officer. The primary factor in setting salary levels pursuant to these arrangements was the desire to provide compensation in amounts sufficient to induce these individuals to either join or continue with us. Salary levels for executive officers reflect the Compensation Committee's judgments on appropriate salaries in light of the duties and responsibilities inherent in the executives' positions. The particular qualifications of an individual holding the position and his or her level of experience, as well as information concerning compensation paid by other companies in the industry, are considered in establishing salary levels. The Compensation Committee's assessment of the individual's performance and contribution to our performance are the primary criteria influencing decisions regarding salary adjustments.

*Stock Options.* We use stock options as a long-term incentive program for our executive officers. Stock options are used because they directly relate the amounts earned by the executive officers to the amount of appreciation realized by our shareholders over comparable periods. Stock options also provide executive officers with the opportunity to acquire and build a meaningful ownership interest. The Compensation Committee considers stock option awards throughout the year. In determining the number of options awarded to an individual executive officer, the Compensation Committee generally establishes a level of award based upon the position of the individual and his or her level of responsibility, and upon recommendations made by the President and Chief Executive Officer. The Compensation Committee's decisions concerning individual option awards are based on its judgment concerning the appropriate amount of long-term compensation that should be paid to the executive in question. On July 30 2001, 15,000 stock options, 50% of which will vest on July 30, 2003 and 50% of which will vest on July 30, 2005 were granted as a long-term incentive to an executive officer who is not a Named Executive Officer, as a condition of his employment. Since 176,250 stock options were awarded to the Named Executive Officers in December 1999, and in light of the vesting schedule relating to those option grants, no stock options were awarded during 2001 to the Named Executive Officers. A total of 98,674 stock options were awarded during 2001 under our Amended and Restated 1996 Key Employees and Consultants Stock Option Plan (the "1996 Plan").

Along with the Board of Directors, we have approved the authorization of an amendment to increase, to 1,057,667, the number of our common shares available for issuance under our 1996 Plan. This will allow us to continue to have access to a sufficient number of stock options, in order to provide incentives to our executive officers and other employees. In addition, the Board of Directors has approved the authorization of an amendment to increase, to 400,000, the number of our common shares available for issuance under our 1999 Director Plan.

**Bonuses.** We may pay additional compensation in the form of discretionary bonuses to our executive officers. The bonus amount in any given year is determined by the Compensation Committee, taking into account several factors, including the executive officer's salary and position, the executive officer's performance and our overall performance. Bonuses may be provided either in the form of cash, common shares or a combination of the two, as the Compensation Committee determines. Dr. Summa received a bonus in the amount of \$7,330 during 2001.

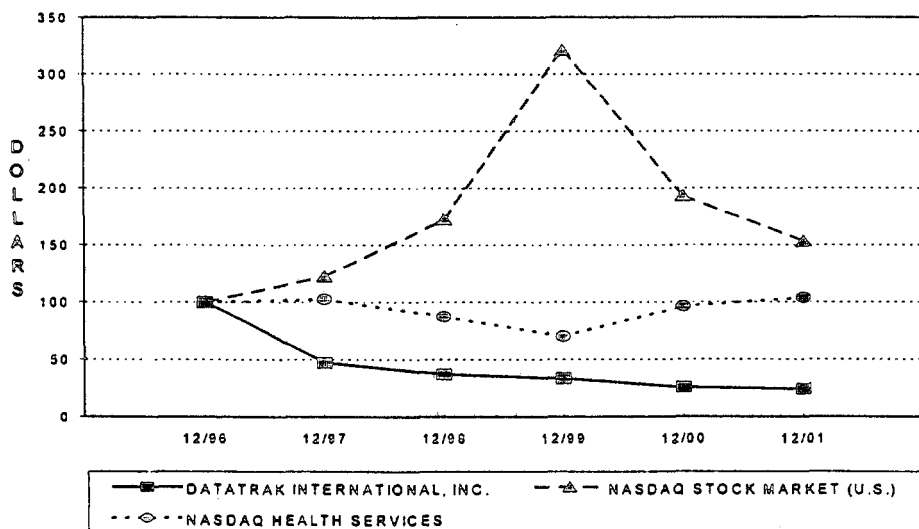
**President and Chief Executive Officer Compensation.** Dr. Green's employment contract contemplates compensation in two broad areas: (1) a base salary and (2) stock options under a long-term compensation plan. His employment agreement provided for a base salary of \$180,000 for 2001. Dr. Green did not receive a bonus in 2001, nor was Dr. Green awarded any options to purchase Common Shares during 2001.

#### THE COMPENSATION COMMITTEE

Robert E. Flaherty (Chairman)  
Seth B. Harris  
Dr. Robert M. Stote

#### Performance Chart

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*  
AMONG DATATRAK INTERNATIONAL, INC.,  
THE NASDAQ STOCK MARKET (U.S.) INDEX  
AND THE NASDAQ HEALTH SERVICES INDEX



\* \$100 invested on 12/31/96 in stock or index-  
including reinvestment of dividends.  
Fiscal year ending December 31.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table shows, as of February 28, 2002 unless otherwise indicated, the beneficial ownership of our common shares of (1) each person who is known to us to own beneficially more than 5% of our outstanding common shares, (2) each of our Directors, (3) each of the Named Executive Officers and (4) all Directors and Named Executive Officers as a group. Unless otherwise indicated, all information with respect to beneficial ownership has been furnished by each Director or Named Executive Officer, as the case may be.

<u>Name and Address of Beneficial Owner</u>	<u>Common Shares Beneficially Owned (1)</u>	
	<u>Number</u>	<u>Percent</u>
Dr. Jeffrey A. Green (2).....	359,993	6.7%
Timothy G. Biro (3) .....	38,200	*
Seth B. Harris (4) .....	141,634	2.7%
Terry C. Black .....	54,543	1.0%
Marc J. Shlaes .....	40,750	*
Dr. Wolfgang Summa .....	28,750	*
Dr. Robert M. Stote .....	69,353	1.3%
Dr. Mark J. Ratain .....	75,500	1.4%
Dr. Jerome H. Kaiser .....	27,100	*
Robert E. Flaherty .....	36,500	*
Brantley Venture Partners II, L.P. .... 20600 Chagrin Boulevard, Suite 1150 Cleveland, Ohio 44122	295,412	5.6%
State of Wisconsin Investment Board (5) .....	781,670	14.8%
P.O. Box 7842 Madison, Wisconsin 53707		
Barnett & Co. as nominee for Boston Partners Small Cap Value Fund II (5) ... c/o Deutsche Bank 16 Wall Street, 4 <sup>th</sup> Floor, Window 44, Ref: Account # 018204 New York, New York 1005	340,000	6.5%
Dolphin Offshore Partners, L.P. (5) .....	400,000	7.6%
c/o Dolphin Asset Management Co. 129 E. 17 <sup>th</sup> Street New York, New York 1003		
Dimensional Fund Advisors, Incorporated (6) .....	270,200	5.1%
1299 Ocean Avenue, 11th Floor Santa Monica, California 90401		
Kyle Krueger (7) .....	337,219	6.4%
150 Second Avenue, North, Suite 860 St. Petersburg, Florida 33701		
All Directors and Named Executive Officers as a group (10 persons) .....	872,323	15.2%

\* Less than one percent.

- (1) The number of common shares deemed outstanding includes (1) 5,263,836 of our common shares outstanding as of February 28, 2002 and (2) with respect to each of the following individuals and groups, the following number of our common shares, which may be purchased pursuant to option exercises within 60 days after February 28, 2002: Dr. Green (95,000 common shares); Mr. Biro (38,000 common shares); Mr. Harris (39,500 common shares); Dr. Stote (39,500 common shares); Dr. Ratain (66,500 common shares); Mr. Flaherty (36,500 common shares); Mr. Black (50,625 common shares); Mr. Shlaes (40,750 common shares); Dr. Summa (28,750 common shares); Dr.

Kaiser (22,500 common shares); Brantley Venture Partners II, L.P. ("Brantley") (5,166 common shares); all Directors and Named Executive Officers as a group (457,625 common shares).

- (2) Includes 73,969 common shares held by Dr. Green's wife. Dr. Green disclaims beneficial ownership of these 73,969 common shares.
- (3) Includes 200 common shares held by Mr. Biro's wife.
- (4) Includes 44,634 common shares held in trust for Mr. Harris.
- (5) The information provided herein, with respect to the beneficial ownership of our common shares held by the State of Wisconsin Investment Board, Barnett & Co. as nominee for Boston Partners Small Cap Value Fund II and Dolphin Offshore Partners, L.P., was obtained solely from our Form S-3 filed with the Commission on January 29, 2002.
- (6) Certain investment companies and certain other commingled group trusts and commingled accounts, for which Dimensional Fund Advisors, Incorporated ("Dimensional") serves in the capacity as investment advisor, hold our common shares listed. Dimensional possesses voting and/or investment power over our common shares listed; however Dimensional disclaims beneficial ownership of these securities. The information provided herein, with respect to the beneficial ownership of our common shares by Dimensional, was obtained solely from the Schedule 13G filed with the Commission on January 30, 2002 by Dimensional.
- (7) The common shares listed are registered in the name of Kyle and Ann Krueger, as joint tenants by the entirety. Includes 292,025 common shares directly owned by Apollo Capital Management Group, L.P. ("ACMG"), which are beneficially owned by ACMG's general partner Apollo Capital Corp. ("Apollo"). Mr. and Mrs. Krueger are each a director, officer and shareholder of Apollo. Also includes 15,900 common shares directly owned by Apollo MicroCap Partners, L.P. ("AMP"), which are beneficially owned by AMP's general partner Bayshore Capital Corp. ("Bayshore"). Mr. and Mrs. Krueger are each a director, officer and shareholder of Bayshore. The information provided herein, with respect to the beneficial ownership of our common shares by Mr. Krueger, was obtained solely from the Schedule 13G filed with the Commission on January 16, 2002 by Mr. Krueger.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In connection with various financing transactions, we have entered into agreements with several of our Directors, executive officers and shareholders who beneficially own more than 5% of our common shares. Since these arrangements were the result of arm's length negotiation with these shareholders prior to their acquisition of our common shares, we believe that the agreements are on terms no less favorable to us than could have been obtained from unaffiliated third parties.

As a result of various financing transactions, we are a party to a registration rights agreement with Brantley, Drs. Green and Stote and Mr. Harris, each of whom is either a Director, executive officer or beneficial owner of 5% or more of our common shares. Under the terms of the registration rights agreement, the holders of 334,001 our common shares (the "Registrable Shares") have the right to demand, no more than once every six months, registration of our common shares having a market value of at least \$5,000,000 (in the case of a registration on Form S-1) or \$1,000,000 (in the case of a registration on Form S-2 or S-3) under the Securities Act. Such demand right may be exercised by the holders of at least 40% of the Registrable Shares. The holders of Registrable Shares may exercise their right to demand registration of the Registrable Shares on Form S-1 up to two times at our expense, and any demand registrations on Form S-2 or S-3 an unlimited number of times at our expense. Although the holders of Registrable Shares have the right to demand additional registrations on Form S-1, they will be required to pay their share of the expenses associated with such registrations. The registration rights agreement also provides the holders of 240,198 our common shares (the "Related Shares"), with the limited right to participate, at their own expense, in a registration statement demanded by the holders of Registrable Shares. In addition, under



certain conditions, the holders of Registrable Shares and Related Shares have the limited right to include some or all of such shares in any registration statement filed by us with respect to the sale of our common shares.

As a result of our private placement, we are a party to a share purchase agreement that grants registration rights to the purchasers of our common shares issued in the private placement. Under the terms of the share purchase agreement, the holders of an aggregate of 1,922,514 our common shares, along with the holders of 192,252 warrants to purchase our common shares, require us to register such shares, at our expense, under the Securities Act prior to May 4, 2002. The holders of the shares purchased in the private placement are permitted to participate, at our expense, in any other registration of our common shares under the Securities Act, until such time as the shares purchased in the private placement are registered under the Securities Act.

#### **PART IV**

##### **ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

###### **(a)(1) Financial Statements**

See Item 8 of Part II of this Annual Report on Form 10-K.

###### **(a)(2) Financial Statement Schedules**

We have included all applicable financial statement schedules in our consolidated financial statements or the related footnotes included elsewhere in this Annual Report on Form 10-K.

###### **(a)(3) Exhibits**

See the Index to Exhibits at page E-1 of this Annual Report on Form 10-K.

###### **(b) Reports on Form 8-K.**

No reports were filed on Form 8-K during the last quarter of the period covered by this Annual Report on Form 10-K.

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

DATATRAK INTERNATIONAL, INC.

/s/ Jeffrey A. Green  
Jeffrey A. Green  
President and Chief Executive Officer

Date: March 27, 2002

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>
<u>/s/ Jeffrey A. Green</u> Jeffrey A. Green	President and Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ Terry C. Black</u> Terry C. Black	Vice President of Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)
<u>/s/ Timothy G. Biro</u> Timothy G. Biro	Director
<u>/s/ Seth B. Harris</u> Seth B. Harris	Director
<u>/s/ Robert M. Stote</u> Robert M. Stote	Director
<u>/s/ Jerome H. Kaiser</u> Jerome H. Kaiser	Director
<u>/s/ Robert E. Flaherty</u> Robert E. Flaherty	Director
<u>/s/ Mark J. Ratain</u> Mark J. Ratain	Director

Date: March 27, 2002

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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## REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Shareholders  
DATATRAK International, Inc.

We have audited the accompanying consolidated balance sheets of DATATRAK International, Inc. and subsidiaries (the "Company") as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of DATATRAK International, Inc. and subsidiaries at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG LLP

Cleveland, Ohio  
February 1, 2002

## DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	December 31,	
	2001	2000
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 2,174,445	\$ 2,383,244
Short-term investments	3,029,582	9,656,852
Accounts receivable, net	429,911	609,351
Taxes receivable	197	130,386
Notes receivable - current	59,164	6,114
Prepaid expenses	314,142	240,712
Total current assets	6,007,441	13,026,659
Property and equipment		
Equipment	4,297,065	3,160,914
Leasehold improvements	135,669	135,669
	4,432,734	3,296,583
Less accumulated depreciation	2,858,523	1,922,231
	1,574,211	1,374,352
Other assets		
Notes receivable - long term	4,487	76,607
Other assets	47,431	8,382
	51,918	84,989
Total assets	<u>\$ 7,633,570</u>	<u>\$ 14,486,000</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 253,095	\$ 129,038
Current portion of capital lease obligation	129,417	-----
Accrued expenses	864,611	914,114
Deferred revenue	469,275	338,879
Total current liabilities	1,716,398	1,382,031
Capital lease obligation, less current portion	162,367	-----
Shareholders' equity		
Serial Preferred Shares, without par value; authorized 1,000,000 shares; none issued	-----	-----
Common shares, without par value, authorized 15,000,000 shares; issued 6,591,322 shares as of December 31, 2001 and 6,590,322 as of December 31, 2000; outstanding 3,291,322 shares as of December 31, 2001 and 3,290,322 shares as of December 31, 2000	50,372,239	50,356,667
Treasury shares, 3,300,000 shares at cost	(20,188,308)	(20,188,308)
Accumulated deficit	(24,341,439)	(16,987,206)
Foreign currency translation	(87,687)	(77,184)
Total shareholders' equity	5,754,805	13,103,969
Total liabilities and shareholders' equity	<u>\$ 7,633,570</u>	<u>\$ 14,486,000</u>

See accompanying notes.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	For the Year Ended December 31,		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Revenue	\$ 2,245,631	\$ 1,993,785	\$ 5,811,165
Direct costs	<u>1,779,501</u>	<u>1,596,355</u>	<u>3,762,843</u>
Gross profit	466,130	397,430	2,048,322
Selling, general and administrative expenses	7,209,789	5,725,846	5,870,869
Depreciation and amortization	<u>949,770</u>	<u>867,484</u>	<u>800,495</u>
Loss from operations	(7,693,429)	(6,195,900)	(4,623,042)
Other income (expense):			
Interest income	382,483	888,385	1,313,427
Interest expense	(19,491)	-----	-----
Gain on sale of Clinical Business	-----	-----	12,154,827
Other income (expense)	<u>(23,796)</u>	<u>23,768</u>	<u>1,258,330</u>
Income (loss) before income taxes	(7,354,233)	(5,283,747)	10,103,542
Income tax expense	<u>-----</u>	<u>-----</u>	<u>384,000</u>
Net income (loss)	<u>\$ (7,354,233)</u>	<u>\$ (5,283,747)</u>	<u>\$ 9,719,542</u>
Net income (loss) per share:			
Basic:			
Net income (loss) per share	\$ <u>(2.23)</u>	\$ <u>(1.61)</u>	\$ <u>1.87</u>
Weighted average shares outstanding	<u>3,290,514</u>	<u>3,290,322</u>	<u>5,208,535</u>
Diluted:			
Net income (loss) per share	\$ <u>(2.23)</u>	\$ <u>(1.61)</u>	\$ <u>1.84</u>
Weighted average shares outstanding	<u>3,290,514</u>	<u>3,290,322</u>	<u>5,293,486</u>

See accompanying notes.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

	Common Shares		Treasury Shares		Retained Earnings	Foreign Currency	Total
	Number of Shares	Stated Amount	Number of Shares	Cost	(Accumulated Deficit)	Translation Adjustments	
<b>Balance at January 1, 1999</b>	6,422,872	\$ 49,704,742	-----	\$ -----	\$(21,423,001)	\$ (44,041)	\$ 28,237,700
Exercise of common share options	167,450	510,111					510,111
Stock compensation		21,700					21,700
Tender of common shares	(3,300,000)		3,300,000	(20,188,308)			(20,188,308)
Comprehensive income:							
Foreign currency translation						5,252	5,252
Net income					9,719,542		9,719,542
Comprehensive income					9,719,542	5,252	9,724,794
<b>Balance at December 31, 1999</b>	3,290,322	50,236,553	3,300,000	(20,188,308)	(11,703,459)	(38,789)	18,305,997
Stock compensation		120,114					120,114
Comprehensive loss:							
Foreign currency translation						(38,395)	(38,395)
Net loss					(5,283,747)		(5,283,747)
Comprehensive loss					(5,283,747)	(38,395)	(5,322,142)
<b>Balance at December 31, 2000</b>	3,290,322	50,356,667	3,300,000	(20,188,308)	(16,987,206)	(77,184)	13,103,969
Exercise of common share options	1,000	800					800
Stock compensation		14,772					14,772
Comprehensive loss:							
Foreign currency translation						(10,503)	(10,503)
Net loss					(7,354,233)		(7,354,233)
Comprehensive loss					(7,354,233)	(10,503)	(7,364,736)
<b>Balance at December 31, 2001</b>	3,291,322	\$ 50,372,239	3,300,000	\$(20,188,308)	\$(24,341,439)	\$ (87,687)	\$ 5,754,805

See accompanying notes

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Year Ended December 31,		
	2001	2000	1999
<b>Operating Activities</b>			
Net income (loss)	\$ (7,354,233)	\$ (5,283,747)	\$ 9,719,542
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Gain on sale of Clinical Business	-----	-----	(12,154,827)
Depreciation and amortization	949,770	867,484	800,495
Accretion of discount on investments	(307,600)	(748,790)	(1,115,730)
Stock compensation	14,772	120,114	21,700
Other	18,000	49,373	100,536
Changes in operating assets and liabilities:			
Accounts and taxes receivable	291,629	(401,862)	(370,648)
Prepaid expenses	(73,430)	21,924	(40,867)
Other assets	(39,049)	551	7,240
Accounts payable and accrued expenses	74,554	(103,284)	(2,056,527)
Deferred revenue	130,396	307,919	(279,449)
Net cash used in operating activities	<u>(6,295,191)</u>	<u>(5,170,318)</u>	<u>(5,368,535)</u>
<b>Investing Activities</b>			
Purchases of property and equipment	(689,718)	(1,029,494)	(746,434)
Sale of business (net of cash sold)	-----	-----	15,601,184
Maturities of short-term investments	28,035,000	48,385,285	242,206,142
Purchases of short-term investments	(21,100,130)	(42,718,276)	(233,044,816)
Other	-----	-----	4,625
Net cash provided by investing activities	<u>6,245,152</u>	<u>4,637,515</u>	<u>24,020,701</u>
<b>Financing Activities</b>			
Purchase of treasury shares	-----	-----	(20,188,308)
Payments under capital lease obligation	(101,416)	-----	-----
(Issuance) repayment of notes receivable	19,070	(19,304)	(63,417)
Proceeds from issuance of shares	800	-----	510,111
Net cash used in financing activities	<u>(81,546)</u>	<u>(19,304)</u>	<u>(19,741,614)</u>
Effect of exchange rate on cash	(77,214)	(26,052)	(21,735)
Increase (decrease) in cash and cash equivalents	<u>(208,799)</u>	<u>(578,159)</u>	<u>(1,111,183)</u>
Cash and cash equivalents at beginning of year	<u>2,383,244</u>	<u>2,961,403</u>	<u>4,072,586</u>
Cash and cash equivalents at end of year	<u>\$ 2,174,445</u>	<u>\$ 2,383,244</u>	<u>\$ 2,961,403</u>
Cash paid during the year for interest	<u>\$ 19,491</u>	<u>\$ -----</u>	<u>\$ -----</u>
Net cash paid during the year for income taxes	<u>\$ -----</u>	<u>\$ 103,795</u>	<u>\$ 192,170</u>

*See accompanying notes.*



**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Years Ended December 31, 2001, 2000 and 1999**

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**1. Accounting Policies**

*Description of Business*

DATATRAK International, Inc. ("DATATRAK" or the "Company") and its wholly-owned subsidiary, DATATRAK GmbH, are Application Service Providers ("ASP") that provide electronic data capture ("EDC") and other services, which assist companies in the clinical pharmaceutical, biotechnology, contract research organization ("CRO") and medical device research industries, to accelerate the completion of clinical trials. Prior to April 20, 1999, the Company also managed a network of non-owned affiliated and owned clinical research sites, which provided Phase I through IV clinical research services, and over the counter product services (the "Clinical Business"). The Clinical Business was sold on April 20, 1999.

*Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

*Revenue Recognition*

DATATRAK – DATATRAK contracts provide a fixed price for each component or service to be delivered, and revenue is recognized as these components or services are delivered. Services provided by DATATRAK that are in addition to those provided for in its contracts are billed on a fee for service basis as services are completed. As services are performed over the life of the contract, revenue is recognized per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Pass-through costs that are paid directly by the Company's clients, and for which the Company does not bear the risk of economic loss, are excluded from revenue. The termination of a contract will not result in a material adjustment to the revenue or costs previously recognized. DATATRAK is also a seller and licensor of software. Generally, revenue is recognized upon delivery of sold software. Licensing revenue is recognized ratably over the life of the license. To date DATATRAK has not recognized any revenue from software sales.

*Clinical Business* – Revenue and related direct costs of revenue were recognized as specific contract terms were fulfilled under the percentage of completion method (the units of delivery method). Fees for individual contract services were fixed upon execution of the contract and provided for payment for all work performed.

*Concentration of Credit Risk*

The Company is subject to credit risk through accounts receivable and short-term investments. The Company generally does not require collateral and the majority of its accounts receivable are unsecured. Short-term investments are placed with high credit-quality financial institutions or in short-duration with high credit-quality debt securities. The Company limits the amount of credit exposure in any one institution or type of investment instrument.

*Cash Equivalents*

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Investments in cash equivalents are carried at cost which approximates market value.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued  
For the Years Ended December 31, 2001, 2000 and 1999

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*Short-term Investments*

Short-term investments are comprised of U.S. Treasury securities and obligations of U.S. government agencies, obligations of states and other political subdivisions, and U.S. corporate obligations with maturities of one year or less. These securities are stated at amortized cost, which approximates fair value. The Company has the positive intent and ability to hold the securities to maturity.

*Property and Equipment*

Property and equipment are stated at cost. Depreciable assets consist of office and computer equipment, software, and software development costs and leasehold improvements. Depreciation and amortization on office and computer equipment and software, and software development costs is computed using the straight-line method over estimated useful lives of 3 to 7 years. Leasehold improvements are amortized using the straight-line method over the lesser of the assets' estimated useful life or the lease term. Depreciation and amortization expense related to depreciable assets was \$950,000, \$870,000 and \$780,000 for 2001, 2000 and 1999, respectively.

Included in equipment at December 31, 2001, is equipment under capital lease recorded at a cost of \$393,000. Amortization expense in 2001 and accumulated amortization related to this equipment at December 31, 2001 was \$98,000.

*Deferred Revenue*

Deferred revenue represents cash advances received in excess of revenue earned on on-going contracts. Payment terms vary with each contract but may include an initial payment at the time the contract is executed, with future payments dependent upon the completion of certain contract phases or targeted milestones. In the event of contract cancellation, the Company is entitled to payment for all work performed through the point of cancellation.

*Stock Based Compensation*

The Company accounts for stock based compensation in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25").

*Impairment of Long-Lived Assets*

The Company evaluates impairment of long-lived assets in accordance with Financial Accounting Standards Board Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of". As such, the carrying values of long-lived assets are evaluated if circumstances indicate a possible impairment in value. If undiscounted cash flows over the remaining amortization period indicate that long-lived assets may not be recoverable, the carrying value will be reduced by the estimated shortfall of cash flows on a discounted basis.

*Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that might affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

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*Financial Instruments*

The carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are reasonable estimates of fair value due to the short-term nature of these financial instruments. Investments are reported at amortized cost, which approximates fair value.

*Advertising Costs*

Advertising costs are expensed as incurred and are included in selling, general and administrative expenses. Advertising expenses were \$380,000, \$270,000 and \$100,000 for 2001, 2000 and 1999, respectively.

*Software Development Costs*

Development costs incurred in the research and development of new software products and enhancements to existing software products are expensed as incurred until technological feasibility has been established. After technological feasibility is established, any additional costs are capitalized in accordance with Statement of Financial Accounting Standards No. 86, "Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed". Such costs are amortized over the lesser of three years or the economic life of the related product. The Company performs an annual review of the recoverability of such capitalized software costs. At the time a determination is made that capitalized amounts are not recoverable based on the estimated cash flows to be generated from the applicable software, any remaining capitalized amounts are expensed.

Unamortized software and software development costs included in the Company's balance sheet were \$110,000, \$70,000 and \$390,000 at December 31, 2001, 2000 and 1999, respectively. Amortization expense related to capitalized software costs was \$120,000, \$330,000 and \$330,000 in 2001, 2000 and 1999, respectively. During 1999, \$30,000 of unamortized software development costs were expensed.

Research and development expenses included in selling, general and administrative expenses were \$1.7 million, \$890,000 and \$590,000 in 2001, 2000 and 1999, respectively.

*Foreign Currency Translation*

The assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars at current exchange rates. Revenue and expense accounts of these operations are translated at average rates prevailing during the period. These translation adjustments are accumulated in a separate component of shareholders' equity. Foreign currency transaction gains and losses are included in determining net income (loss) when realized.

**2. Notes Receivable**

The Company has loans outstanding to an officer in the amount of \$52,685 and \$66,213 at December 31, 2001 and 2000, respectively. The loans bear interest at 5.0%, compounded monthly, and are due on demand.

The Company also has an employee loan outstanding in the amount of \$10,966 and \$16,508 at December 31, 2001 and 2000, respectively, of which \$6,479 is payable to the Company in 2002. The loan bears interest at 5.5%, compounded monthly.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
For the Years Ended December 31, 2001, 2000 and 1999

**3. Short-term Investments**

The following is a summary of held-to-maturity securities:

	December 31, 2001		December 31, 2000	
	<u>Cost</u>	<u>Amortized Cost</u>	<u>Cost</u>	<u>Amortized Cost</u>
U.S. Treasury securities and obligations of U.S. government agencies	\$ 502,904	\$ 503,712	\$ ---	\$ ---
Obligations of states and political subdivisions	---	---	1,935,500	1,978,858
U.S. corporate obligations	2,507,016	2,525,870	7,570,466	7,677,994
	<u>\$ 3,009,920</u>	<u>\$ 3,029,582</u>	<u>\$ 9,505,966</u>	<u>\$ 9,656,852</u>

**4. Accounts Receivable**

Accounts receivable consist of the following:

	December 31,	
	<u>2001</u>	<u>2000</u>
Trade accounts receivable:		
Billed	\$ 342,228	\$ 543,959
Unbilled	148,066	74,868
Total trade accounts receivable	420,294	618,827
Other	4,117	37,024
Allowance for doubtful accounts	(64,500)	(46,500)
	<u>\$ 429,911</u>	<u>\$ 609,351</u>

Movement of the allowance for doubtful accounts is as follows:

	Year ended December 31,		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Balance at beginning of year	\$ 46,500	\$ 30,000	\$ 158,000
Provision for uncollectible accounts	18,000	16,500	28,000
Sale of Clinical Business	----	----	(154,000)
Uncollectible accounts written off	----	----	(2,000)
Balance at end of year	<u>\$ 64,500</u>	<u>\$ 46,500</u>	<u>\$ 30,000</u>

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

**5. Accrued Expenses**

Accrued expenses consist of the following:

	<u>December 31,</u>	
	<u>2001</u>	<u>2000</u>
Contract service costs	\$ 8,213	\$ 101,299
Payroll and other employee costs	552,737	371,664
Professional fees	227,043	292,214
Other	76,618	148,937
	<u>\$ 864,611</u>	<u>\$ 914,114</u>

**6. Income Taxes**

Due to its net losses, the Company had no federal, state or local income tax expense in 2001 and 2000. During 1999, the Company had \$92,000 of federal income tax expense and \$292,000 of state and local income tax expense due to the gain on the sale of its owned clinical business.

A reconciliation of income taxes (benefit) at the United States Federal statutory rate to the effective income tax rate is as follows:

	<u>Year ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Income taxes (benefit) at the United States statutory rate	\$(2,500,400)	\$(1,796,500)	\$ 3,435,200
Non - U.S. income taxes	53,000	61,600	363,500
State and local income taxes	----	----	192,700
Net operating loss carryback (carryforward)	----	----	(1,629,300)
Federal alternative minimum tax	----	----	92,000
Change in valuation allowance	2,483,000	1,779,000	(3,804,000)
Allowances, accruals and other	(35,600)	(44,100)	1,733,900
	<u>\$ ---</u>	<u>\$ ---</u>	<u>\$ 384,000</u>

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued  
For the Years Ended December 31, 2001, 2000 and 1999

At December 31, 2001 the Company had a net operating loss carryforward of approximately \$17.2 million, for United States income tax purposes, which will expire through the year 2021. The Company also had a net operating loss carryforward of approximately \$4.4 million, for German income tax purposes, with no expiration date. The significant components of the Company's deferred tax assets (liabilities) are as follows:

	December 31,	
	2001	2000
Deferred tax assets (liabilities):		
U.S. net operating loss carryforwards	\$ 5,852,000	\$ 3,871,000
Non - U.S. net operating loss carryforwards	1,717,000	1,263,000
Alternative minimum tax credit	92,000	92,000
Allowances and accruals	218,000	138,000
Depreciation and amortization	(102,000)	(70,000)
	<u>7,777,000</u>	<u>5,294,000</u>
Valuation allowance	(7,777,000)	(5,294,000)
Net deferred tax assets recorded	<u>\$ ---</u>	<u>\$ ---</u>

#### 7. Operating Leases

The Company leases certain office equipment and space. Rent expense relating to these operating leases was approximately \$390,000, \$280,000 and \$490,000 in 2001, 2000 and 1999, respectively. In December 2001, the Company entered into a 7.5-year lease agreement for office space in Cleveland, Ohio. Future minimum lease payments and sublease receipts for the Company under noncancelable operating leases as of December 31, 2001 are as follows:

<u>Year ending December 31,</u>	<u>Payments</u>	<u>Receipts</u>
2002	\$ 187,528	\$ 31,900
2003	194,460	---
2004	196,020	---
2005	206,340	---
2006	216,660	---
Subsequent to 2006	582,912	---
	<u>\$ 1,583,920</u>	<u>\$ 31,900</u>

#### 8. Shareholders' Equity

##### *Serial Preferred Shares*

At December 31, 2001 and 2000, the Company had 1,000,000 Serial Preferred Shares, without par value, authorized, with none outstanding.

##### *Treasury Shares*

During 1999, the Company completed a tender offer by repurchasing 3.3 million of its common shares at a purchase price of \$6.00 per share. The cost of the tender offer was \$20.2 million.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

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**9. Share Option Plans**

The Company has five share option plans. At December 31, 2001, the Company had reserved 1,433,275 common shares for the exercise of common share options. The Company has granted 1,401,124 options to purchase common shares to employees directors and others. There are 32,251 options to purchase common shares available for future grants. The weighted average contractual life of all options outstanding was 7.3 years as of December 31, 2001. The range of exercise prices for all options outstanding at December 31, 2001 was \$0.15 to \$10.75.

The Amended and Restated 1992 Share Incentive Plan ("1992 Plan") was approved by the Company's shareholders for the purpose of granting common share options to employees and consultants of the Company and its affiliates. Prior to May 1995, options to purchase common shares were granted at exercise prices of less than the fair market value of a common share on the date of grant. Compensation expense related to these options has been previously recognized. Subsequent to April 1995, all options to purchase common shares awarded under the 1992 Plan were granted at exercise prices that represented the fair market value of a common share on the date of grant. All options granted under the 1992 Plan expire ten years after the grant date. At December 31, 2001 there were 127,000 options outstanding under the 1992 Plan with exercise prices ranging from \$0.15 to \$4.15, all of which were 100% vested. These options had a weighted average contractual life of 2.1 years and a weighted average exercise price of \$1.32. There will be no future grants of options under the 1992 Plan.

The Amended and Restated 1994 Directors' Share Option Plan ("Director Plan") was established by the Company, to provide common share options to directors of the Company for their participation in Board of Directors' meetings. All options awarded under the plan have an exercise price per share that was equal to the fair market value of a common share on the date of grant. All options granted under the Director Plan expire ten years after the grant date. At December 31, 2001 there were 6,667 options outstanding under the Director Plan with exercise prices ranging from \$0.80 to \$9.60, all of which were 100% vested. These options had a weighted average contractual life of 3.5 years and a weighted average exercise price of \$5.17. There will be no future grants of options under the Director Plan.

The Amended and Restated 1996 Outside Directors' Stock Option Plan, as amended ("1996 Director Plan") was established by the Company to provide common share options as compensation to directors of the Company. In 1998, the Company's Board of Directors approved the granting of a total of 70,000 Common Share options at an exercise price of \$4.19 per share. The Company's shareholders approved these option grants, at exercise prices below the market value of a common share, on the approval date, in 1999. The Company recognized compensation expense related to these common share options of \$21,700 in 1999. All other options granted under the 1996 Director Plan have been granted at exercise prices that represented the fair market value of a common share on the date of grant. At December 31, 2001 there were 66,500 options outstanding under the 1996 Director Plan with exercise prices ranging from \$4.19 to \$9.60, all of which were 100% vested. These options had a weighted average contractual life of 6.2 years and a weighted average exercise price of \$4.84. There will be no future grants of options under the 1996 Director Plan.

The Amended and Restated 1996 Key Employees and Consultants Stock Option Plan ("1996 Plan") provides for the granting of a maximum of 757,667 options to purchase common shares to key employees and consultants of the Company and its affiliates. During 2000, 77,354 common share options were granted at exercise prices of less than the fair market value of a common share on the date of grant. The Company recognized compensation expense related to these common share options of \$14,772 and \$14,514 in 2001 and 2000, respectively. If all options vest, additional compensation expense of \$30,000 will be recognized through 2004. All other options granted under the 1996 Plan have been granted at exercise prices that represented the fair market value

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

of a common share on the date of grant. Vesting of options awarded under the 1996 Plan is determined by the Company's Compensation Committee, as appointed by the Board of Directors, and all options granted under the 1996 Plan expire ten years after the grant date. At December 31, 2001 there were 672,416 options outstanding under the 1996 Plan with exercise prices ranging from \$2.00 to \$10.75, of which 261,952 were 100% vested. These options had a weighted average contractual life of 8.0 years and a weighted average exercise price of \$4.10.

During 1999, the Company established the 1999 Outside Director Stock Option Plan ("1999 Plan"). The 1999 Plan provides for the granting of a maximum of 250,000 options to purchase common shares to outside directors of the Company. In 1999, the Company's Board of Directors approved the granting of a total of 72,500 Common Share options at exercise prices of \$3.63 and \$3.75 per share. The Company's shareholders approved these option grants, at exercise prices below the market value of a common share, on the approval date, in 2000. The Company recognized compensation expense related to these common share options of \$105,600 in 2000. No further compensation expense will be recorded related to these common share options. All other options granted under the 1999 Plan have been granted at exercise prices that represented the fair market value of a common share on the date of grant. Options fully vest one year following the grant date. All options granted under the 1999 Plan expire ten years after the grant date. At December 31, 2001 there were 222,500 options outstanding under the 1999 Plan with exercise prices ranging from \$2.00 to \$5.19, of which 147,500 were 100% vested. These options had a weighted average contractual life of 8.5 years and a weighted average exercise price of \$3.64.

The Company's share option activity and related information is summarized below:

	Year ended December 31,					
	2001		2000		1999	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of period	919,242	\$ 4.00	666,089	\$ 3.83	444,650	\$ 4.69
Granted	176,841	2.30	270,434	4.58	495,489	3.78
Exercised	(1,000)	0.80	---	---	(167,450)	3.05
Cancelled	---	---	(17,281)	6.33	(106,600)	8.44
Outstanding at end of period	1,095,083	\$ 3.73	919,242	\$ 4.00	666,089	\$ 3.83
Exercisable at end of period	609,619	\$ 2.95	354,350	\$ 3.20	252,600	\$ 4.06

#### 10. Stock Based Compensation

The Company has elected to follow APB 25 and related interpretations in accounting for its employee and director stock options. As discussed below, the alternative fair value accounting provided for under Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25 compensation expense has been recognized for all options granted at less than the fair market value of the common shares on the date of grant.



**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

Pro forma information regarding net income and earnings per share is required by SFAS 123, which also requires that the information be determined as if the Company has accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The following assumptions were used to determine the fair value for these options using a Black-Scholes option pricing model.

	Year ended December 31		
	2001	2000	1999
Risk free interest rate	4.9%	6.5%	5.5%
Volatility factor of the expected market price of the common shares	0.66	0.57	0.34
Dividend yield	0.0%	0.0%	0.0%
Weighted-average expected life of the option	7 years	7 years	7 years
Weighted-average fair value per share of options granted	\$1.45	\$3.34	\$2.18

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated value of the options is amortized to expense over the options' vesting period. The pro forma results are not necessarily indicative of what would have occurred had the Company adopted SFAS 123. The Company's pro forma information follows:

	Year ended December 31,		
	2001	2000	1999
Pro forma net income (loss)	\$ (7,844,762)	\$ (5,805,030)	\$ 8,899,528
Pro forma basic income (loss) per share	\$ (2.65)	\$ (1.88)	\$ 1.81
Pro forma diluted income (loss) per share	\$ (2.65)	\$ (1.88)	\$ 1.78

#### **11. Retirement Savings Plan**

The Company sponsors The DATATRAK International, Inc. Retirement Savings Plan (the "Plan") as defined by Section 401(k) of the Internal Revenue Code of 1986, as amended. The Plan covers substantially all employees who elect to participate. Participants may contribute up to 20% of their annual compensation into a variety of mutual fund options. Matching and profit sharing contributions by the Company are discretionary. The Company did not make any matching or profit sharing contributions in 2001, 2000 or 1999.

#### **12. Segment Information**

Prior to April 20, 1999, the Company operated in two principal business segments: The DATATRAK EDC Business and the Clinical Business. The Clinical Business was sold on April 20, 1999. The DATATRAK EDC Business provides EDC technology and other services to assist various clinical trial sponsors and CROs in the timely completion of clinical trials. The Clinical Business, a multi-specialty site management organization, provided Phase I through IV clinical research services and over-the-counter product services. Subsequent to April 20, 1999, the Company operates only the DATATRAK EDC Business.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

Information on the Company's business segments for 1999 is as follows:

<u>Year ended December 31, 1999</u>	<u>DATATRAK EDC Business</u>	<u>Clinical Business</u>	<u>Total</u>
Revenue:	\$ 900,388	\$ 4,910,777	\$ 5,811,165
Depreciation and amortization:	670,630	129,865	800,495
Income (loss) from operations:	(4,917,535)	294,493	(4,623,042)
Expenditures for long-lived assets:	737,717	8,717	746,434

*Enterprise-Wide Disclosures*

*Geographic Information*

<u>Year ended December 31,</u>	<u>United States</u>	<u>Germany</u>	<u>Total</u>
Revenue:			
2001	\$ 1,785,745	\$ 459,886	\$ 2,245,631
2000	1,541,921	451,864	1,993,785
1999	5,598,946	212,219	5,811,165
Income (loss) before income taxes:			
2001	(5,131,023)	(2,223,210)	(7,354,233)
2000	(2,995,743)	(2,288,004)	(5,283,747)
1999	11,544,934	(1,441,392)	10,103,542
Long-lived assets at December 31,			
2001	1,365,426	208,785	1,574,211
2000	1,080,525	293,827	1,374,352

*Major Customers* — During 1999, the Clinical Business recorded revenue of approximately \$1.0 million from one customer.

The following sets forth the revenue generated by customers who accounted for more than 10% of the Company's DATATRAK EDC revenue during each of the periods presented (in thousands):

	<u>Year ended December 31,</u>		
<u>Customer</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>
A	\$496	\$548	\$251
B	511	*	*
C	465	*	*
D	250	1,030	430

\* Less than 10% of revenue.

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
**For the Years Ended December 31, 2001, 2000 and 1999**

**13. Net Income (Loss) Per Share**

The following table sets forth the computation of basic and diluted earnings per share.

	Year Ended December 31,		
	2001	2000	1999
Net income (loss) used in the calculation of basic and Diluted earnings per share	\$ (7,354,233)	\$ (5,283,747)	\$ 9,719,542
Denominator for basic net income (loss) per share -- weighted average common shares outstanding	3,290,514	3,290,322	5,208,535
Effect of dilutive common share options	---	---	84,951
Denominator for diluted net income (loss) per share	3,290,514	3,290,322	5,293,486
Basic net income (loss) per share	\$ (2.23)	\$ (1.61)	\$ 1.87
Diluted net income (loss) per share	\$ (2.23)	\$ (1.61)	\$ 1.84
Common share options excluded from the computation of diluted net income (loss) per share because they would have an antidilutive effect on net income (loss) per share	1,095,083	919,242	212,576

**14. Capital Lease Obligation**

During March 2001, the Company entered into an agreement with an unaffiliated third party to lease certain computer equipment in the amount of \$393,200, which is excluded from the Company's consolidated statement of cash flows. The lease has been recorded as a capital lease. Terms of the lease agreement require the Company to maintain a restricted cash balance equal to the outstanding balance payable on the lease (\$291,784 at December 31, 2001). Future minimum lease payments under the capital lease obligation as of December 31, 2001 are as follows:

<u>Twelve months ending December 31,</u>	
2002	\$ 145,089
2003	145,089
2004	24,181
	<u>314,359</u>
Less amounts representing interest	22,575
	<u>\$ 291,784</u>

**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued**  
For the Years Ended December 31, 2001, 2000 and 1999

**15. Quarterly Data (Unaudited)**

Selected quarterly data is as follows (in thousands):

	Year Ended December 31, 2001			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 673	\$ 400	\$ 477	\$ 696
Gross profit (loss)	243	(29)	45	207
Loss from operations	(1,730)	(1,839)	(2,027)	(2,097)
Net loss	(1,591)	(1,736)	(1,967)	(2,060)
Net loss per share: basic	(0.48)	(0.53)	(0.60)	(0.63)
Net loss per share: diluted	(0.48)	(0.53)	(0.60)	(0.63)

	Year Ended December 31, 2000			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 497	\$ 435	\$ 517	\$ 545
Gross profit	146	68	41	142
Loss from operations	(1,301)	(1,641)	(1,578)	(1,676)
Net loss	(1,055)	(1,412)	(1,346)	(1,471)
Net loss per share: basic	(0.32)	(0.43)	(0.41)	(0.45)
Net loss per share: diluted	(0.32)	(0.43)	(0.41)	(0.45)

**16. Liquidity and Subsequent Events**

The Company incurred net losses of \$7,354,000 in 2001 and \$5,284,000 in 2000. As of December 31, 2001, the Company's cash and short-term investments were \$5,204,000 as compared to \$12,040,000 as of December 31, 2000. The Company's viability to continue as a going concern is dependent upon customer acceptance of EDC services, management's ability to raise additional capital and ultimately, a return to profitability.

Management's plans to improve operating results and cash flow include the reorganization of its sales force, which occurred in the second half of 2001, and continuing efforts to raise additional capital. Should management fail in these initiatives, it will implement cost cutting measures in order to reduce its operating expenses and capital expenditures.

In connection with management's plan described above, on January 7, 2002, the Company completed a private placement of its common shares with certain outside investors. The Company sold 1,922,514 of its Common Shares at a price of \$2.25 per share. Net of expenses, the Company raised approximately \$4.0 million in cash. In conjunction with this private placement, DATATRAK issued 192,252 warrants to purchase common shares at a price of \$2.25 per share. The warrants are fully vested as of the grant date and expire five years from the date of grant.

Management believes that as a result of the capital raised in January 2002 and continued implementation of its plan to improve operating results, the Company will be able to meet its obligations over the next twelve months.

## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>	<u>Page</u>
3.1	Fifth Amended and Restated Articles of Incorporation	(1)
3.2	Certificate of Amendment to the Fifth Amended and Restated Articles of Incorporation dated April 20, 1999	(2)
3.3	Certificate of Amendment to the Fifth Amended and Restated Articles of Incorporation dated September 22, 1999	(3)
3.4	Third Amended and Restated Code of Regulations	(1)
3.5	Certificate of Amendment to the Third Amended and Restated Code of Regulations	(4)
4.1	Specimen Certificate of the Company's Common Shares, without par value	(5)
4.2	Second Amended and Restated Registration Agreement, dated July 25, 1994, as amended on June 1, 1995 and February 5, 1996	(6)
10.1	Amended and Restated 1994 Directors' Share Option Plan*	(7)
10.2	Amended and Restated 1996 Outside Directors' Stock Option Plan*	(7)
10.3	Amendment No. 2 to the Amended and Restated 1996 Outside Directors' Stock Option Plan*	(2)
10.4	Amended and Restated 1992 Share Incentive Plan*	(7)
10.5	Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan*	(7)
10.6	1999 Outside Director Stock Option Plan*	(8)
10.7	Form of Indemnification Agreement*	(6)
10.8	Employment Agreement between the Company and Jeffrey A. Green, dated February 5, 2001*	(9)
10.9	Employment Agreement between the Company and Terry C. Black, dated February 5, 2001*	(9)
10.10	Separation Agreement between the Company and Terry C. Black, dated December 22, 1998*	(10)
10.11	Employment Agreement between the Company and Wolfgang Summa, dated December 29, 2000*	(9)
10.12	DATATRAK International, Inc. Retirement Savings Plan*	(11)
21.1	Subsidiaries of the Company	

# Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>	<u>Page</u>
23.1	Consent of Ernst & Young LLP	
<hr/>		
*	Management compensatory plan or arrangement.	
(1)	Incorporated herein by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (File No. 000-20699).	
(2)	Incorporated herein by reference to the Company's Schedule 14A filed on March 17, 1999 (File No. 000-20699).	
(3)	Incorporated herein by reference to the Company's Form S-8 Registration Statement filed on November 10, 1999 (File No. 333-90699).	
(4)	Incorporated herein by reference to the Company's Schedule 14A filed on October 31, 2001 (File No. 000-20699).	
(5)	Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 1999 (File No. 000-20699).	
(6)	Incorporated herein by reference to the Company's Form 1 Registration Statement filed on March 8, 1996, as amended by Amendment No. 1 filed on May 10, 1996 and as amended by Amendment No. 2 filed on June 10, 1996 (File No. 333-2140).	
(7)	Incorporated herein by reference to the Company's Form S-8 Registration Statement filed on November 13, 1996 (File No. 333-16061).	
(8)	Incorporated herein by reference to the Company's Schedule 14A filed on April 28, 2000 (File No. 000-20699).	
(9)	Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 2000 (File No. 000-20699).	
(10)	Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 1998 (File No. 000-20699).	
(11)	Incorporated herein by reference to the Company's Form S-8 Registration Statement filed on April 30, 1997 (File No. 333-26251).	

## Board of Directors

Timothy G. Biro  
General Partner  
Ohio Innovation Fund I, L.P.  
(venture capital firm)

Robert E. Flaherty  
President and Chief Executive Officer  
Athena Diagnostics, Inc.  
(pharmaceutical and medical diagnostics  
manufacturer)

Jeffrey A. Green, Pharm.D., FCP  
President and Chief Executive Officer

Seth B. Harris  
Chairman, Frieder the Source  
(consumer products distributor)

Jerome H. Kaiser, Ph.D.  
Senior Vice President  
and Director of Information Services  
Rothschild, Inc  
(investment bank firm)

Mark J. Ratain, M.D.  
Medical Oncologist, Professor of Medicine  
and Chairman, Committee on Clinical  
Pharmacology, University of Chicago

Robert M. Stote, M.D.  
Senior Vice President  
Chief Science Officer, and a Director  
Bentley Pharmaceuticals, Inc.  
(pharmaceutical manufacturer)

## Transfer Agent and Registrar

Inquiries related to share certificates, changes of  
address, and general correspondence concerning  
shareholder accounts please contact:

Shareholder Services  
National City Bank  
Stock Transfer Operations  
P.O. Box 92301  
Cleveland, OH 44193-0900  
or, by telephone (800) 622-6757

## Executive Officers

Dr. Jeffrey A. Green  
President, Chief Executive Officer and  
Director

Terry C. Black  
Vice President of Finance,  
Chief Financial Officer and Treasurer

Marc J. Shlaes  
Vice President of Research and Development

Dr. Wolfgang Summa  
Vice President of Global Operations

Mark J. Levine  
Executive Vice President of Global Business  
Development

Thomas F. McKee  
Secretary

## Annual Meeting

DATATRAK's Annual Meeting of Shareholders  
will be held in Suite 100 of the Paragon II  
Building, 6150 Parkland Boulevard, Mayfield  
Heights, Ohio, on June 4, 2002 at 10:00 a.m.

## General Counsel

Calfee, Halter & Griswold LLP  
Cleveland, Ohio

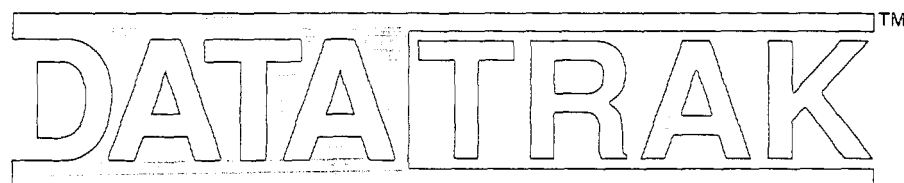
## Independent Auditors

Ernst & Young LLP  
Cleveland, Ohio

## Investor Information

Investor inquiries should be directed to:

Investor Relations  
DATATRAK International, Inc.  
6150 Parkland Boulevard, Suite 100  
Mayfield Heights, Ohio USA 44124  
Telephone (216) 921 - 6505



I N T E R N A T I O N A L

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